UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

FILED UNDER SEAL
PURSUANT TO 31U.S.C. §3730

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUSIANA, THE STATE OF MARYLAND, THE STATE OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW HAMPSHIRE, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF VIRGINIA, THE STATE OF WASHINGTON, THE STATE OF WISCONSIN AND THE DISTRICT OF COLUMBIA, *ex rel.* JOHN R. BORZILLERI, M.D. Plaintiffs, BAYER AG, BIOGEN IDEC, INC., PFIZER, INC., EMD SERONO, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., NOVARTIS AG, EXPRESS SCRIPTS HOLDING COMPANY, CVS CAREMARK CORPORATION, CATAMARAN CORPORATION, UNITEDHEALTH GROUP, INC., HUMANA, INC., WELLPOINT, INC., CIGNA CORPORATION, AETNA, INC. AND WELLCARE HEALTH PLANS, INC. Defendants.	CIVIL ACTION NO. CV-14-03-ML RELATOR'S FIRST AMENDED COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §3729 *et seq.];* AND SUPPLEMENTAL STATE FALSE CLAIMS ACTS **JURY TRIAL DEMANDED**

RELATOR'S COMPLAINT

NATURE OF THE ACTION

1. John R. Borzilleri, M.D. ("Relator"), a physician and professional healthcare investment fund manager, brings this Qui Tam action on behalf of the United States, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the State of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Virginia, the State of Wisconsin, the State of Washington and the District of Columbia (the *"Plaintiff States"* and collectively with the United States, the *"Government Plaintiffs"*), for violations of the Federal False Claims Act, 31 U.S.C. §3729-33 ("FCA") *et seq.*, as well as for violations of the following State False Claims Acts: the California False Claims Act, Cal Government Code §§12650 *et seq*.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310; the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301b; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 *et seq*.; the Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq*.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 *et seq*.; Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 *et seq*.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 *et seq*.; the Indiana Whistleblower Reward and Protection Act, Indiana Code §5-11-5.5; the Iowa False Claims Act, Iowa Code §§ 685.1 through 685.7; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 *et seq*.; the Maryland False Health Claims Act, MD Code Ann., Health-Gen. § 2-602 (a) (1). (2); the Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A *et seq*.; the Michigan Medicaid False Claims Act, MCLS §§400.601 *et seq*.; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 through 15C.16; the Montana False Claims Act, Mont. Code Anno. §§17-8-401 *et seq*.; the Nevada False Claims Act, Nev. Rev. Stat. §§357.010 *et seq*.; the New Hampshire False Claims Act, RSA tit. XII, Ch. 167:61-b; The New Jersey False Claims Act, N.J. Stat. §2A:32C-1 *et seq*.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§27-14-1 *et seq*.; the New York False Claims Act, NY CLS St. Fin. §§187 *et seq*.; the North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-606 *et seq*.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § §5053 *et seq*.; the Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 *et seq*.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-171 *et seq*.; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 *et seq*.; the Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 *et seq*.; the Washington Medicaid Fraud False Claims Act, Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214; the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931; and the District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 *et seq*. (hereafter referred to as the *"State False Claims Acts"*) to recover all damages, civil penalties

and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts against the following Defendants, and their affiliates, subsidiaries, agents, successors and assigns: Bayer AG, Biogen Idec, Inc., Pfizer, Inc., EMD Serono, Inc., Teva Pharmaceutical Industries, Ltd and Novartis AG (hereafter referred to collectively as the *"Manufacturer Defendants")*; as well as Express Scripts Holding Company, CVS Caremark Corporation, Catamaran Corporation, UnitedHealth Group, Inc., Humana, Inc., Wellpoint, Inc., Cigna Corporation, Aetna, Inc. and Wellcare Health Plans, Inc. (hereafter referred to as the *"Pharmacy Benefit Manager (PBM) Defendant*s").

PREAMBLE - MEDICARE PROGRAM

2. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). There are four major components to the Medicare program:

(a) Part A, the hospital insurance benefits program.

(b) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services.

(c) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries.

(d) Part D, the voluntary prescription drug benefit program.42 U.S.C. § 1395w-101, et seq.

3. Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, which set up a voluntary prescription benefits program for Medicare enrollees. Part D became effective January 1, 2006. Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D *"sponsors"* to administer prescription drug plans. Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan ("PDP"), a Medicare Advantage organization plan ("MA-PD plan), or a Program of All-Inclusive Care for the Elderly ("PACE").

4. A Part D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month ("PMPM") cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium.

5. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy.

6. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. 42 C.F.R. § 423.505(k)(1). If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. 42 C.F.R. § 452.505(k)(3).

7. Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

8. Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with PBMs. PBMs can provide a variety of services to sponsors to help manage their prescription drug benefit. These services include processing prescription drug claims, contracting with pharmacies, managing formularies, as well as negotiating rebates with drug manufacturers. PBMs can be compensated for these services in a variety of ways, including receiving a fixed payment per claim or retaining a percentage of sponsors' rebates.

9. PBMs can also be directly compensated by drug manufacturers via designated "Bona Fide Service Fees" (BFSFs) for a wide array of product-related "services", such as inventory management, patient education, phone support, shipping, reimbursement assistance, data reports, etc., which would have otherwise been performed by the manufacturer. BFSFs are excluded from government *"negotiated price"* calculations, thus leading to higher drug reimbursement prices and greater manufacturer revenues/profits.

SUMMARY OF FRAUD ALLEGATIONS

10. John R. Borzilleri, M.D. ("Relator") has ascertained that the Manufacturer Defendants of multiple sclerosis (MS) drugs have made fraudulent overpayments of "*Bona Fide Service Fees"* (BFSFs) far in excess of the legally-required *"Fair Market Value"* (FMV) to the PBM Defendants, as part of a nationwide collusive scheme in the Medicare Part D program. The Relator has discovered a pattern of systemic, on-going fraud which may only be readily discerned by reviewing/studying/considering all of the investigative work contained in this complaint. This initial complaint focuses on the Manufacturer Defendants specialty drugs used for the treatment of multiple sclerosis (MS) because it provides the clearest evidence of FMV BFSF fraud in Medicare Part D. However, the Relator avers the fraudulent practice is occurring in other drug therapeutic categories in Medicare Part D as well, including treatments for cancer, diabetes and inflammatory conditions (rheumatoid arthritis, psoriasis, etc.).

11. The Manufacturer Defendants have paid these fraudulent FMV BFSFs primarily via service contracts (typically based upon a percent of product sales) with the PBM Defendants, inclusive of massive, collusive drug price increases. The fraudulent FMV BFSFs scheme has resulted in a nearly five-fold increase (from the $12,000 per patient just prior to the 2006 start of Part D to the $50,000-60,000 per patient range at the end of 2013) in the US price for the Manufacturer Defendants MS drugs in Medicare Part D. See **Exhibit 1** in the **Appendix**. The massive increase in US MS drug prices and service fees has occurred despite a significant decline in patient usage for the Manufacturer Defendants' MS drugs. This directional inconsistency is counter to any reasonable *"competitive market"* rationale.

12. In fact, the Relator avers that fraudulent FMV BFSFs, rather than manufacturer rebates/discounts as anticipated by the Part D legislation, are the primary method of compensation from the Manufacturer Defendants to the PBM Defendants in Medicare Part D. Legitimate BFSFs payments from manufacturers to service vendors are provided primarily for patient and volume-based services, such as inventory management, distribution/shipping services, patient support and clinical programs. The Relator has determined that legitimate BFSFs paid by the Manufacturer Defendants to the PBM Defendants, related to the respective MS drugs, should rightfully have been in significant decline since 2006 due to the deteriorating US patient usage for the drugs.

13. Based upon a stable *"percent of revenue"* service contract estimate, inclusive of the massive price increases, the Relator alleges that the Manufacturer Defendants are paying the PBM Defendants approximately five times as much BFSFs per MS patient in 2013 compared to 2005, just before the start of Medicare Part D. Using an estimated *"4% of sales"* service contract rate to illustrate the trends, the Relator estimates that the BFSFs paid per Part D MS patient have increased from approximately $465 in 2005 to more than $2,200 in

2013. See **Exhibit 2.** This estimated five-fold increase in BFSFs per beneficiary has occurred despite a 35-40% decrease in US drug usage for the Manufacturer Defendants MS drugs and a commensurate decrease in legitimate patient/volume-based *"bona fide"* service needs. As such, the Relator alleges that the vast majority of the increased BFSFs paid per MS patient in Part D have greatly exceeded FMV and are therefore fraudulent.

14. At a 4% service contract rate, the Relator estimates cumulative fraudulent FMV BFSFs of nearly $900 million in the combined US Commercial/Part D MS specialty drug market between 2006 and 2013. Due to greater MS drug spending growth in Part D, the Relator estimates the Part D share of the BFSF fraud at 12% in 2006, rising to 25% in 2013. Overall, the Relator estimates fraudulent Part D FMV BFSFs, paid by the Manufacturer Defendants to the PBM Defendants, of approximately $220 million between 2006 and 2013, with the fraud ongoing. Of note, the Relator considers the 4% *"per cent of sales"* service contract estimate to be conservative. As discussed later in the complaint, investigation and direct industry feedback suggests that PBM Defendant service contract rates may be considerably higher, and on the rise, in many instances due to escalating PBM Defendants negotiating leverage in the oligopolistic PBM industry. The true magnitude of the alleged FMV BFSF fraud will be determined by a review of confidential service contract terms, as well as other financial transactions, between the Defendant parties during discovery.

15. While the direct BFSF fraud in this case is considerable, the Relator seeks restitution for the far larger amount of fraudulent Part D Manufacturer Defendant MS drug revenues enabled by the collusive pricing scheme. Of note, the Relator excluded an estimate of heavily-discounted MS drug sales to Medicaid and other price-controlled government programs from these fraud estimates. In the Relator's view, due to severe competitive pressures and declining usage, the Relator is confident that NONE of the five-fold price increase for the long-marketed Manufacturer Defendants MS drugs in Part D would have occurred without BFSFs-related collusion with the dominant PBM Defendants.

16. Assuming flat drug pricing at year-end 2005 levels in the $12,000/beneficiary/year range, the Relator estimates fraudulent overpayment by CMS of approximately $4.5 billion for the Manufacturer Defendant MS drugs in Part D between 2006 and 2013, with the fraud ongoing. See **Exhibit 3.** In addition, due the compounding and relentless nature of the extreme price collision, the magnitude of both the BFSF and related Part D MS drug revenue fraud has sharply increased each year since the start of Part D. The Relator estimates fraudulent Part D Manufacturer Defendant MS drug revenues of approximately $68 million in 2006, rising to more than $1.4 billion in 2013.

17. Although, perhaps outside the scope of this Qui Tam filing, the Relator has concluded that the collusive Manufacturer and PBM Defendants pricing scheme related to the fraudulent FMV BFSFs in Medicare Part D, has been the driving factor behind extreme MS drug price inflation in the commercial

insurance sector, as well. Without the cost insulation to elderly beneficiaries provided by the Part D program, extreme Manufacturer Defendant MS price inflation in the commercial sector simply would not have been possible. In addition to the fraudulent Part D MS overpayment due to the fraudulent FMV BFSFs scheme, the Relator estimates an additional $20 billion in fraudulent MS drug sales in the US commercial insurance sector for the years 2006 through 2013, with the fraud ongoing. See **Exhibit 3**.

18. CMS uses different price calculation methodologies for each of its government drug programs: AMP (Average Manufacturer Price) for Medicaid; ASP (Average Selling Price) for Medicare Part B; and *"negotiated price"* for Medicare Part D. Pertaining to Medicare Part D, CMS depends upon *"private competition"* to determine the *"negotiated price"* for government reimbursement, Part D sponsor reconciliation and future beneficiary premium rates. *42 CFR 423.100.*

19. Central to this complaint, the CMS regulations regarding the handling of BFSFs and the legal requirements of FMV in Medicare Part D have been unequivocally in place since the start of the program in 2006. Furthermore, since at least 2007, the handling of BFSFs and FMV has been virtually identical in the Medicaid, Medicare Part B and Medicare Part D drug programs.

20. The lack of restrictions in the Part D legislation regarding the inter-relationship of Part D sponsors and their subcontractors has also been a key factor enabling the fraud outlined in this complaint. In the Part D regulations, subcontractors are defined as *"First Tier, Downstream or Related Entities" ("FDRs").* CMS defines a *"First Tier Entity"* as *"any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization ("MAO") or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the Medicare Advantage ("MA") program or Part D program. 42 C.F.R. § 423.501. CMS defines a "Downstream Entity" as any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage or Part D benefit, below the level of the arrangement between the Managed Care Organization or applicant or a Part D plan sponsor or applicant and a first tier entity." Chapter 9, Medicare Drug Benefit Manual; C.F.R. Parts 422 and 423.* PBMs and specialty pharmacies are uniformly classified as *"First Tier"* and *"Downstream*" entities, respectively, in Part D. A *"Related Entity"* is defined by CMS as *"any entity that is related to a Managed Care Organization (MAO) or Part D sponsor by common ownership or control".* P*rescription Drug Benefit Manual, Chapter 9 - Compliance Program Guidelines.* Despite what would appear to be significant fraud concerns, the Part D legislation allows all these parties in a particular Part D plan to be closely affiliated and even part of the same ownership structure. Not surprisingly, this lack of conflict-of-interest protection has led to severe consolidation and concentration of service providers in the Medicare Part D program.

21. The PBM Defendants, who control the majority (more than 80%) of Part D enrollment, are fully-integrated service providers, with all key functions (plan sponsor insurance entity, PBM and specialty pharmacy) either under the same ownership structure or closely-affiliated. In Part D, the regulations place the primary CMS reporting responsibilities on the plan sponsor entity, not subcontracted *"First Tier, Downstream and Related"* (FDRs) entities. As such, the Relator recognizes that the PBM Defendants may be employing complex legal and financial arrangements between related subsidiaries in order to obfuscate the FMV BFSF fraud at the center of this case. For instance, PBM Defendants, in their role as plan sponsors, typically keep their PBM and specialty pharmacy subsidiaries as separate legal entities apart from the insurance entity. As such, the PBM Defendants, in practice, may be receiving the fraudulent BFSFs in Medicare Part D related to the Manufacturer Defendants MS drugs through their specialty pharmacy subsidiaries, thus potentially outside of CMS *"sponsor"* reporting requirements.

22. In Medicare Part D, CMS clearly places the legal responsibility for fraud prevention and detection on the plan sponsor regarding all *"First Tier, Downstream and Related" (FDRs)*, including compliance to CMS regulations, the Anti-Kickback Statute (AKA) and the False Claims Act (FCA). *C.F.R. Parts 422 and 423*. However, the Part D regulations also require all FDRs to comply with the same anti-fraud statutes, stating: the *"Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions related to the sponsor's Medicare Parts C and D contracts."* P*rescription Drug Benefit Manual, Chapter 9 - Compliance Program Guidelines.* Furthermore, as per the *Code of Federal Regulations* and the related *Medicare Drug Benefit Manual*, Part D plan sponsors and their FDR subcontractors are required to *"certify"* compliance to all applicable law, including the AKA, in order to participate in Medicare Part D. As such, the PBM Defendants, by knowingly accepting fraudulent BFSF payments, directly violate the FCA and the AKA in their roles as plan sponsors, PBMs and specialty pharmacies.

23. In the US pharmaceutical industry, varying drug pricing benchmarks are commonly employed for both manufacturer/service vendor contracts and for drug reimbursement. The lack of pricing benchmark standards creates variability, uncertainty, lack of transparency and controversy regarding the *"confidential"* service contracts between the Manufacturer and PBM Defendants in Medicare Part D. For instance, *"Average Wholesale Price"* (AWP) is a benchmark that has been used for over 40 years for the pricing and reimbursement of prescription drugs for both government and private payers. However, in recent years, AWP has increasingly been viewed as a *"list price"*, typically 15-20% over the *"market price"* actually paid by large distributors and PBMs (commonly called *"Wholesale Acquisition Cost"* (WAC)). *Drugs.com.* Despite its elevated and inaccurate nature, AWP is still commonly used as the basis for reimbursement for both government and private payers. In its 2013 10K on file with the Security and Exchange Commission (SEC), Express Scripts, the largest US PBM, admits that AWP remains a key pricing benchmark in its contracts.

Express Scripts stated: *"Contracts in the prescription drug industry, including our contracts with retail pharmacy networks and with PBM and specialty pharmacy clients, generally use "average wholesale price" or "AWP", which is published by a third party as a benchmark to establish pricing for prescription drugs."* On the other hand, pharmacies, including specialty pharmacies, often purchase drugs based upon the discounted *"Wholesale Acquisition Cost"* (WAC). The difference between the price paid by the pharmacy and AWP is known as the *"spread"*, which equates to the potential profit that the pharmacy receives. The Relator's analysis and industry insider commentary indicate that manufacturer *"Market Approach/Percent of Revenue"* contracts with service vendors are typically based on WAC price levels.

24. The Relator has determined that BFSF payments far in excess of FMV from the Manufacturer Defendants to the PBM Defendants are the primary path of the fraud in this case. However, the typically wide 15-20% *"spread"* between AWP and WAC drug prices may provide opportunity for additional undisclosed fraudulent payments between the Manufacturer and PBM Defendants, such as rebates/discounts related to *"spread"* pricing. The PBM Defendants could decide not to disclose these payments as discounts to CMS by locating the fees within *"legally distinct"* specialty pharmacy subsidiaries that fall outside of Part D plan sponsor reporting requirements. However, the Relator believes such a practice would be a direct violation of the Part D legislation, which requires plan sponsors to provide beneficiaries with full access to prices *"negotiated*" with drug manufacturers.

25. Furthermore, CMS has made it clear that it considers all payments to Service Vendors, other than BFSFs, to be price discounts/concessions that must be included in *"negotiated price"* calculations. As stated in the Medicare Part D DIR *("Direct and Indirect Remunerations")* Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: *"CMS considers all remunerations received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide service fees, to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor."* As such, exclusion of *"spread"* profits within specialty pharmacy subsidiaries from mandated DIR reports would be in direct violation of the CMS regulations.

26. In the collusive scheme, the Manufacturer Defendants are knowingly compensating the PBM Defendants in Medicare Part D with excessive, fraudulent service fees (i.e., illegitimate BFSFs) via service contracts (typically as a % of product sales) inclusive of massive, collusive price increases. As discussed later in the complaint, the Relator has uncovered extensive evidence of the standard industry practice of *"market-based/percent of revenue"* service fee contracts, without adjustment for severe price increases. The intentional purpose by both Defendant parties in this service fee scheme is to escalate Part D MS drug prices to their mutual financial benefit, while knowingly hiding the fraudulent BFSF payments from CMS.

27. The Defendants are able to employ BFSFs in this nationwide fraudulent scheme because the CMS regulations pertaining to BFSFs in Part D:

a) Do not limit the amount of BFSFs that can be paid by drug manufacturers to PBMs and specialty pharmacies;
b) Do not require manufacturers or PBM entities to report BFSFs to CMS, and;
c) Allow drug manufacturers/PBMs to exclude all *"legitimate"* BFSFs from Medicare Part D "*negotiated price"* calculations.

28. However, the *"Achilles Heel"* facing both the Manufacturer and PBM Defendants in this scheme is the clear CMS regulatory requirement that all BFSFs in Medicare Part D be paid at *"Fair Market Value"* (FMV) commensurate with an *"arm's length"* transaction between unaffiliated parties. From the start of Medicare Part D, CMS has placed the clear legal responsibility for proper BFSF FMV determination on drug manufacturers. The requirement is stated clearly in the Code of Federal Regulations governing Part D at *CFR 423.50,* which states: "*Bona fide service fees means fees paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title of the drug"*.

29. Both the manufacturer Part D legal requirement regarding the FMV of BFSFs, as well as Federal concerns regarding potential for fraud in the handling of these fees, have been reiterated by numerous federal authorities since the 2006 start of the program. In fact, CMS continues to purposely keep its guidance regarding FMV vague due to concerns about potential fraud, reiterating in its February 2012 proposed rule: *"We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define 'fair market value' at this time."* Recently, CMS reiterated the manufacturer responsibility regarding the FMV assessment of BFSFs in its 2012 DIR (*"Direct and Indirect Remunerations"*) reporting requirements, stating: *"We believe manufacturers are well-equipped to determine the most appropriate industry-accepted method for determining fair market value of drug distribution services for which they contract." Final Medicare Part D DIR Reporting Requirements for 2012, June 7, 2013.*

30. By law, any fee amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in *"excess"* of FMV must be reported to CMS as price concessions *(i.e., "Direct and Indirect Remuneration")* which serve to lower drug costs in Medicare Part D. This requirement was reiterated in CMS's *Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011,* which states: *"In the case of rebate administration fees or other amounts from*

pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4."

31. By paying BFSFs far in excess of FMV to the PBM Defendants that serve to fraudulently escalate US MS drug prices, the Manufacturer Defendants are knowingly causing the collusive PBM Defendants to submit fraudulent *"claims for payment"*, in the form of Prescription Drug Event (PDE) data for each relevant prescription, to CMS. The Part D regulations clearly indicate that PDE data filed by PBMs (either in their role as plan sponsors or as *"First Tier"* contractors to other plan sponsors) is in fact a *"claim for payment"*. The *"payment claim"* status of PDE data was definitely confirmed recently by both the Court Order and the United States Statement of Interest (to the Defendant's Motion to Dismiss) related to the active Qui Tam case, the *United States of America, ex. rel. Anthony R. Spay v. CVS Caremark Corporation*.

32. By willfully paying and receiving *"kickbacks" (i.e., "payments for referral"*) in the form of fraudulent FMV BFSFs, both the Manufacturers and PBM Defendants have also directly violated both the AKA and the FCA. Legal precedent has clearly established violations of the AKA as a direct basis for a FCA violation. For instance, in *the United States ex. rel. Thompson v. Columbia/HCA Healthcare Corporation*, the Fifth Circuit court ruled that the relator could state a cause for action under the FCA claim if the government's decision to pay claims was conditioned upon the defendants' certification of compliance with pertinent laws. *See Thompson, 125 F. 3d at 902-3.* On remand, the District court supported this decision specifically for Medicare based upon an affidavit from the acting chief of the Health Care Financing Administration (HCFA), which stated: *"HCFA conditions both the payment and provider eligibility on the veracity of the provider's certification in the cost report that all services were provided in compliance with applicable law, specifically the AKA". U.S. ex. rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F.Supp.2d 1017, 1041-42, 1046 (S.D. Tex. 1998)*. Other key relevant cases include *United States ex rel. Pogue v. American Healthcorp* and *United States ex rel. McNutt v. Haleyville Medical Supply, Inc*. However, to further allay any confusion, the Affordable Care Act (ACA) in 2010 amended the Federal Anti-Kickback laws to state that any claim submitted to a Federal or State healthcare program which violates the AKA is also a false claim under the FCA.

33. Through investigation, the Relator has determined that virtually all legitimate *"services"* provided by PBMs and specialty pharmacies for manufacturer specialty drugs are based upon patient usage and drug volume. As such, without the collusive scheme, the amount of legitimate BFSFs paid by the Manufacturer Defendants to the PBM Defendants would rightfully have been in significant decline between 2006 and 2013, commensurate with approximate 35-40% decline in patient usage for the Defendant Manufacturers MS drugs due to severe new drug competition. Based upon reliable public data (prescription databases, pricing

databases and the Manufacturer Defendants' own financial reports), the Relator estimates that, without the collusive pricing scheme, the US sales of the Manufacturer Defendants MS drugs would have declined by approximately 40% from the $2.5 billion range in 2005 to the $1.4 billion range in 2013. See **Exhibit 3**. However, counter to any rationale competitive dynamics, reported US sales for the five Manufacturer Defendants drugs nearly tripled from 2006 to approximately $7.1 billion in 2013, due to unprecedented price collusion between the Manufacturer Defendants and the nine PBM Defendants that control the majority of Medicare Part D enrollment. In fact, the Relator's investigation has determined that the collusion between the Manufacturer and PBM Defendants is so pervasive that the massive price inflation for all the Manufacturer Defendants MS drugs has occurred in near lockstep between 2006 and 2013 for virtually all Part D plans across the nation. These troubling trends are indicative of a nationwide collusive pricing scheme of unprecedented magnitude.

34. However, the signs of collusive pricing activity have accelerated even further recently, following the March 2013 US launch of Biogen's new oral therapy, Tecfidara. With Tecfidara rapidly taking market share, the erosion in usage of the Manufacturer Defendants older MS drugs has further accelerated. Virtually all of Tecfidara's 11.6% US market share gain in the mature MS market in 2013 has come at the expense of the five Manufacturer Defendants MS drugs, with the greatest share losses for Biogen's Avonex and Teva's Copaxone. See **Exhibit 4**. As of the fall of 2013, the US prescriptions for the older Defendants' MS drugs were declining 11-30% year-over-year. The Relator estimates combined US patient usage for the older Defendants' MS drugs (Biogen's Avonex, Teva's Copaxone, Serono/Pfizer's Rebif, Bayers's Betaseron and Novartis's Extavia) declined another 20% in 2013 alone, with now a cumulative decline of 35-40% since the start of Medicare Part D. See **Exhibit 3**.

35. Despite the accelerating erosion in usage, combined US sales of the Defendants' older injectable MS drugs actually increased by approximately 8% in 2013 due to a further acceleration in already severe price inflation. See **Exhibits 1 & 3**. Following additional significant price increases, the annual cost of therapy for the older Defendant MS drugs has risen from the $41,000 range in 2012 to nearly $59,000 (before manufacturer rebates/discounts) by December 2013. Due to the severe competitive pressures, the Relator is certain this accelerating price inflation would not be possible without the collusive fee scheme at the center of this complaint.

36. CMS has established a unique bid and reimbursement process in the administration of Part D with plan sponsors. Under Medicare Part D, plan sponsors are required to submit bids to CMS in the first week of June for the following calendar plan year. The bids are based upon the sponsor's estimate of its anticipated monthly drug costs for Part D beneficiaries in the plan, as well as administrative costs and expected profit. *(OIG Report, Medicare Part D Reconciliation Payments for 2006 and 2007, OEI-02-08-*

00460, September 2009). CMS uses the submitted data to determine individual plan premium rates and monthly Subsidy payments made to plan sponsors for the following calendar plan year. The monthly Subsidy payment schedule of Part D is designed to help plans effectively manage *"cash flow"* during a plan year as actual drug costs accrue.

37. The plan sponsor bid cost estimates and related monthly Subsidy payments consist of four distinct tranches. First, the sponsor must provide a cost estimate for the *"basic"* Part D benefit for a beneficiary of *"average"* health in the plan, for which it receives monthly *"Regular Subsidy"* payments. According to CMS, the *"Regular Subsidy"* monthly payments for Part D plans across the US are relatively similar since the amounts are based upon national beneficiary cost averages, with modest adjustments for age and health status in each particular plan. Second, the plan sponsor must provide an estimate of the benefit cost for low-income (LIS) beneficiaries in the plan for the following calendar year, for which CMS provides monthly *"Low-Income (LIS) Subsidy"* payments. LIS beneficiaries are low-income elderly and disabled people, who commonly are afflicted with severe chronic medical conditions necessitating the use of high-priced specialty drugs. In Part D, the LIS population has comprised 30% of overall enrollment each year of the program, with this beneficiary segment accounting for about 70% of overall specialty drug spending. CMS covers virtually all drug costs for LIS beneficiaries in Medicare Part D. Third, the sponsor must estimate the cost of providing *"catastrophic"* drug coverage for non-LIS beneficiaries (70% of Part D enrollment) whose annual out-of-pocket spending exceeds the annual maximum threshold ($3,600 in 2006, rising to $4,750 in 2013). For *"catastrophic"* drug costs, CMS covers 80% of the estimated costs via monthly *"Reinsurance Subsidy"* payments; with plan sponsors and non-LIS beneficiaries responsible for 15% and 5% of spending over the threshold. In Part D, the use of high-priced specialty drugs is the primary driver of crossing the annual Catastrophic spending threshold. In contrast to *"Regular Subsidy"* payments, monthly *"LIS Subsidy"* and *"Reinsurance Subsidy"* payments among plans can vary widely, depending upon the enrollment and health status characteristics of a particular plan. Finally, starting in 2011, CMS added the *"Gap Discount Subsidy"* as part of the ACA legislation, which requires drug manufacturers to provide price discounts to all Part D beneficiaries in the so-called *"donut hole"* coverage window. In plan bid submissions, plan sponsors must estimate the amount of manufacturer *"donut hole"* discounts for the following calendar year, for which CMS provides monthly *"Gap Discount Subsidy"* payments. Since CMS hired a Third Party Administrator (TPA), Palmetto GBA, to administer the Gap Discount program, the *"Gap Discount Subsidy"* payments appear to be *"pass through"* amounts from manufacturers to plans sponsors. The Relator does not consider *"Gap Discount Subsidy"* payments to be a key conduit for the alleged FMV BFSF fraud.

38. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile Subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan

sponsors are required to submit a *"Prescription Drug Event"* (PDE*)* record for each prescription for all covered drugs dispensed to enrollees. The PDE includes 37 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE does not provide drug costs paid by PBMs to drug manufacturers. In addition, sponsors must submit quarterly and year-end DIR *("Direct and Indirect Remuneration")* reports to CMS to disclose any rebates or price concessions, which almost entirely come from manufacturers via PBM negotiations for the vast majority of plans. Of note, both the PDE and DIR data are *"self-reported"*, with apparently limited CMS oversight or verification. *(Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010)*. For the vast majority of Part D plans, the PDE and DIR reports are prepared by contracted PBMs, with limited controls by either CMS or unaffiliated plan sponsors

39. Both *"Low-Income Subsidy"* and *"Reinsurance Subsidy"* plan sponsor payments undergo a reconciliation process after each plan year. In the case of *"Low-Income Subsidy"* payments, CMS guarantees full reimbursement of any cost over-runs, with no risk borne by plans sponsors, PBM subcontractors or drug manufacturers. As such, in the collusive scheme between the Manufacturer and PBM Defendants, both parties garner enormous financial gains from the massive MS drug price increases in the LIS population, while passing all the additional cost on to Federal/State governments, beneficiaries and taxpayers. In reconciliation, the cost-sharing responsibilities for excess non-LIS *"Catastrophic"* drug spending are the same as during the bid process. Namely, CMS covers 80% of unlimited excess costs, with the plan sponsor and beneficiary responsible for 15% and 5%, respectively.

40. Since 2006, the price increases for many specialty drugs, but especially for the Manufacturer Defendants' MS drugs, have far outpaced the modest increases in the annual non-LIS Part D beneficiary out-of-pocket *"Catastrophic Limit"*. While the annual US cost for the Defendant MS drugs has increased nearly five-fold to the $50,000-60,000 range at present, the annual Part D non-LIS beneficiary *"Catastrophic Limit"* has modestly increased from $3,600 in 2006 to $4,750 in 2013. As such, each year since the inception of Medicare Part D, virtually all non-LIS beneficiaries treated with the Defendants' MS drugs exceed the out-of-pocket threshold, and at an accelerating pace and by an ever-widening margin.

41. With these dynamics, the fraudulent Manufacturer Defendants MS drug revenues associated with FMV BFSF fraud are primarily reflected in the skyrocketing *"Reinsurance Subsidy"* payments and escalating *"LIS Subsidy"* costs since the start of Part D. The amount of *"Reinsurance Subsidy"* payments has nearly tripled from $5.5 billion in 2006 to $15.6 billion in 2012, with the majority of this increase attributable to specialty drug price increases rather than increased patient utilization. The annual *"LIS Subsidy"* payments have increased from $15.1 million in 2006 to $22.6 in 2012. See **Exhibit 5**. Together *"Reinsurance"* and *"LIS Subsidy"* payments accounted for 65% of Part D spending in 2012, up from 55% in 2006. Notably, all of the

combined increase is attributable to an increase in the *"Reinsurance Subsidy"* spending share from 15.5% in 2006 to 26.4% in 2012. See **Exhibit 6**. The Relator has determined that the fraudulent price inflation for the Manufacturer Defendants' drugs in the MS category (the largest specialty drug spending category in Part D) has been largest contributor to escalating Part D spending, accounting for up to 40% of the increase in *"Reinsurance"* and *"LIS Subsidy"* annual payments since the start of the program.

42. MedPAC is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare Program. In chapter 5 of its March 2010 report entitled, *"A Data Book: Medicare Part D Program"*, MedPAC discussed potential reasons behind the acceleration in Reinsurance Subsidy payments between the program years 2006 and 2009. MedPAC and the Office of Actuary attributed part of the very high growth rates in the early program years to plan sponsors' relative inexperience at bidding and a lack of good claims data. In addition, MedPAC stated: *"Another force behind the growth in reinsurance spending was the trend in costs for drugs in plans' specialty tiers, which typically are higher priced products that have fewer therapeutic substitutes. Although Part D plan sponsors have an incentive to control drug spending, the degree to which they can control spending is weaker for certain drugs. If one drug can be substituted for another, a plan can bargain with manufacturers that want their product placed on the plan's formulary in a favorable position (e.g., on a preferred vs. non-preferred tier). But if a plan must cover an innovative drug that has no therapeutic substitute, it has little negotiating power over the drug's price."* However, MedPAC appears not to recognize the dominant role of PBMs in Medicare Part D and their shifting financial incentives in the evolving biopharmaceutical industry. Furthermore, the agency similarly does not recognize the considerable variation in competitive dynamics among different US specialty drug categories. As discussed in the Complaint in detail, the *"interchangeable"* nature of the long-marketed Defendant MS drugs, as well as severe new US drug competition, should enable highly-effective *"therapeutic substitution*" and significant price competition in a properly functioning competitive market.

43. In a January 2010 report, the General Accounting Office (GAO) provided details of Part D spending by constituency for the 2007 plan year. See **Exhibit 7**. Consistent with prior comments, LIS beneficiaries accounted for $4.0 billion or 70% of total Medicare Part D specialty drug spending in 2007, with non-LIS accounting for $1.7 billion or 30%. Of the $4.0 billion LIS spending, Medicare paid $3.11 billion (79%), plans paid $0.84 billion (21%) and LIS beneficiaries paid only $10 million (0.2%). Of the $1.7 billion non-LIS spending, Medicare paid $0.70 billion (42%), plans paid $0.63 billion (38%) and non-LIS beneficiaries paid $0.33 (20%). Combining the two populations, beneficiary out-of-pocket payments accounted for only $334 million or 6.0% of overall Medicare Part D specialty drug spending in 2007. The modest Part D beneficiary out-of-pocket exposure to inflating specialty drug costs, driven by the fully government-funded LIS population and CMS's 80% coverage of non-LIS Catastrophic spending, has been an important factor

insulating both the Manufacturer and PBM Defendants from public scrutiny of the severe MS drug price inflation. On the other hand, this same government funding has also greatly increased the financial burden of the alleged fraud on US taxpayers.

44. The Relator has determined that erosion in the traditional US branded pharmaceutical market in recent years due to numerous major patent expirations has provided the Manufacturer and PBM Defendants with the *"cover"* to benefit from massive MS specialty drug price increases related to FMV BFSF fraud. This statement is fully supported by the trends for the three Part D Subsidy payments since the 2006 start of the program. Because the Regular Subsidy for Part D plans is based upon the average drug cost of all beneficiaries in the nation, healthy beneficiaries (whom are the majority in Part D and are limited users of specialty drugs) have the dominant impact on these payments. As such, the 24% decline in the Regular Subsidy per beneficiary between 2006 and 2013 is not surprising given the large number of major traditional US drug patent expirations over the past seven year. See **Exhibit 5**. Notable large traditional pharmaceuticals losing patent protection since 2006 include: Zocor (cholesterol, 2006), Zoloft (depression, 2006), Imitrex (migraines, 2007), Ambien (sleep, 2007), Norvasc (cardiac, 2007), Risperdal (neurologic, 2008), Topomax (neurologic, 2009), Cozaar (cardiac, 2010), Aricept (Alzheimer's, 2010), Lipitor (cholesterol, 2011), Zyprexa (neurologic, 2011), Diovan (cardiac, 2012), Seroquel (neurologic, 2012), Plavix (cardiac, 2012), Singulair (asthma, 2012), Actos (diabetes, 2012), Lexapro (depression, 2012) and Aciphex (ulcers, 2013).

45. On the other hand, the massive increase in *"Reinsurance Subsidies"*, as well as the significant rise in *"LIS Subsidies"*, are both primarily caused by greatly escalating specialty drug costs. Furthermore, according to the biopharmaceutical and PBM industries' own data, the massive escalation in US specialty drug costs in both Medicare Part D and the commercial insurance market has been driven primarily by severe price inflation of already-marketed drugs, not increased utilization or new product introductions.

46. The severe price inflation of the Manufacturer Defendants MS drugs has undoubtedly placed a significant burden on many Part D beneficiaries, especially elderly beneficiaries treated with MS drugs within the larger non-LIS population (70% of Part D enrollment). First, non-LIS Part D beneficiaries are typically responsible for 25-30% of drug costs before reaching the *"donut hole"* coverage window. Second, non-LIS still may have significant drug costs in the *"donut hole"* even after the 2011 start of the mandatory 50% manufacturer *"Gap Discount"* program. Third, non-LIS beneficiaries are still responsible for 5% of drug costs after exceeding the annual catastrophic out-of-pocket spending threshold, which is a considerable dollar amount following the severe price inflation for the Defendant MS drugs in Part D.

47. In 2013, with Part D end-user prices in the $50,000 range per patient for the Defendant MS drugs, the non-LIS beneficiary potential financial exposure is considerable. For instance, including maximum

beneficiary spending of $4,750 before reaching the catastrophic threshold and 5% of the remaining drug cost (5% of $45,250 or $2,263), a self-funded, non-LIS MS Part D beneficiary would be responsible for approximately $7,000 of their annual MS drug costs. See **Exhibit 8**. With the median income and savings for the average Medicare beneficiary in 2013 of $23,500 and $61,400, respectively, many Part D MS patients likely struggle to afford this level of cost-sharing. *Income and Assets of Medicare Beneficiaries, 2013-2030, Kaiser Family Foundation, January 9, 2014.*

48. Yet surprisingly, the public outcry in recent years regarding the extreme US MS drug price inflation has been very modest. Upon investigation, the Relator has determined that the aggressive expansion of Manufacturer-funded Patient Assistance Programs (PAPs) has been a key factor abetting this systemic fraud. For instance, Defendant Biogen's reported PAP funding (for all its products, not just its MS therapies) increased from $100 million in 2007 to $353 million in 2012. *Biogen Annual Reports, 2007-2012.* Of note, with no CMS reporting requirements or standards regarding PAP programs, the disclosed Biogen PAP spending costs may reflect inflated *"retail"* drug prices which may greatly exceed the company's cost of providing financial support, including discounts or free drugs. For reference, Biogen's overall cost of goods for its entire product line has only been in the 12% of sales range in recent years. CMS allows all manufacturer PAP support to be included in annual beneficiary TrOOP (true-out-of-pocket) calculations, thus accelerating attainment of the *"Catastrophic Threshold"*. As such, providing financial support for non-LIS MS beneficiaries to deflect attention from massive price inflation has proved highly strategic for the Manufacturer Defendants, especially since CMS guarantees reimbursement for 80% of the ever-inflating catastrophic drug costs.

49. Of note, the vast expansion of manufacturer PAP spending has occurred despite considerable fraud concerns before the start of Medicare Part D. On November 22, 2005, the Office the Inspector General of the Department of Health and Human Services released in the Federal Register a publication entitled, *"Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D." Federal Register, Vol 70, No. 224, 11/22/2005.* In the Advisory, HHS discussed in considerable detail its concerns regarding the potential anticompetitive impact of PAP programs in the Medicare Part D program. HHS stated: *"Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs, we believe such subsidies for Part D drugs would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse."* Despite considerable evidence of anticompetitive Part D activity, HHS has not released any further comments regarding PAPs or placed any significant restrictions on their use in the more than seven years since the start of the Part D program. As such, manufacturers are able to deflect public scrutiny to massive price inflation by covering some or all of non-LIS beneficiary co-payment and co-insurance cost-sharing requirements. In Part D, CMS has apparently only placed manufacturer restrictions on

the use of drug *"coupons"* (to offset modest co-payment amounts), which are most commonly used for lower cost traditional drugs.

50. Given the severe MS price inflation in Part D, the Manufacturer Defendants financial returns for providing PAP assistance for non-LIS beneficiaries have greatly escalated each year of the program. In **Exhibit 8**, the straightforward financial calculations for a non-LIS MS Part D beneficiary receiving full manufacturer PAP support is provided for the years 2006 and 2013. For this example, the Relator conservatively assumes that the Defendant MS drug is the only pharmaceutical used by the beneficiary. For 2006, assuming an average MS drug cost of $15,000 per patient and the out-of-pocket threshold of $3,600 for that plan year, the beneficiary would be responsible for $570 (5%) of $11,400 of MS drug spending beyond the Catastrophic threshold; CMS and the plan sponsor would be responsible for $9,120 (80%) and $1,710 (15%), respectively. If a Manufacturer Defendant covered all 2006 non-LIS beneficiary cost-sharing requirements both before and after the catastrophic threshold ($4,170), the Manufacturer Defendant would yield $10,830 revenues per patient (before potential discounts/fees to service vendors). For 2013, assuming an average MS drug cost of $50,000 and the out-of-pocket threshold of $4,750, the beneficiary would be responsible for $2,263 (5%) of $45,300 of MS drug spending beyond the catastrophic threshold; CMS and the plan sponsor would be responsible for $36,200 (80%) and $6,788 (15%), respectively. If a Manufacturer Defendant covered all 2013 non-LIS beneficiary cost-sharing requirements ($7,013) both before and after the catastrophic threshold, the Manufacturer Defendant would yield $42,988 for the same patient (before potential discounts/fees to service vendors).

51. Compared to 2006, a Manufacturer Defendant would only have to provide a maximum (assuming full cost-sharing assistance) of an additional $2,843 in PAP assistance to a non-LIS beneficiary in 2013 in order to reap up to an additional $32,158 in revenues for a single drug-treated MS patient. Obviously, this represents an astounding return on the Manufacturer Defendants PAP programs in Medicare Part D. Of course, the actual PAP dollar cost for an individual non-LIS beneficiary to a Manufacturer Defendant may be far lower since these calculations are based upon *"retail"* prices. Non-LIS beneficiaries may also seek financial assistance from other public and private organizations, diminishing the need for Manufacturer Defendant financial support. Finally, deflecting scrutiny in the non-LIS population via PAP programs allows the Manufacturer and PBM Defendants to quietly gain the full price benefit from their collusive scheme in the fully government-funded LIS population, which accounts for the majority of US specialty drug spending.

52. The considerable increase in Manufacturer Defendants non-LIS PAP assistance has no doubt been a key factor deflecting scrutiny from massive MS drug price inflation in Part D. However, a far greater direct financial factor in the alleged fraud has likely been the *"handling"* of escalating Part D plan sponsor cost-sharing responsibilities for non-LIS beneficiaries in the Catastrophic coverage phase. As noted above, after

surpassing the Catastrophic threshold, plan sponsors are responsible for 15% of an unlimited amount of additional drug spending for a beneficiary in any given Part D plan year. Given the extreme inflation of the Manufacturer Defendants MS drugs, the potential financial burden on plan sponsors, including the PBM Defendants, has greatly escalated since the start of Medicare Part D. In 2006, with Manufacturer Defendants MS drug prices in the $15,000 range, 15% plan sponsor exposure above the Catastrophic threshold amounts to $1,710 per non-LIS beneficiary. In contrast, with end-user prices in the $50,000 range in 2013, the plan sponsor cost-sharing exposure above the threshold would be four-fold higher at $6,788 for a non-LIS beneficiary. See **Exhibit 8**.

53. In a normally-functioning competitive marketplace, the significant non-LIS Catastrophic cost-sharing responsibilities would be expected to strongly incent the PBM Defendants to negotiate aggressively with the Manufacturer Defendants for price concessions. However, as CMS's own data clearly indicates (discussed later in detail), massive inflation of the older Manufacturer Defendants MS drugs in virtually all Part D plans across the nation has occurred nonetheless. Given the overall modest margins in the PBM industry (operating margins in the 3-5% range), the Relator has determined that the PBM Defendants would not be able to bear the severe escalation in Catastrophic cost-sharing related to drug price inflation without financial offsets from the Manufacturer Defendants. Furthermore, given their dominant negotiating leverage in Part D and extreme competition in the MS category, the PBM Defendants would not permit the massive price increases without Manufacturer Defendants offsets for the escalating Catastrophic cost-sharing requirements.

54. As with non-LIS beneficiary PAP assistance, the economic incentives for the Manufacturer Defendants, to provide financial assistance to the PBM Defendants for fast-inflating drugs in the Catastrophic coverage period is straightforward. In **Exhibit 8**, the Manufacturer Defendants economics for providing both full beneficiary PAP support and full plan sponsor cost-sharing coverage is provided for the years 2006 and 2013. In 2006, with a MS drug cost of approximately $15,000, if the Manufacturer Defendants covered all non-LIS beneficiary and plan sponsor cost-sharing requirements in the Catastrophic phase ($5,880), each beneficiary would generate revenues of $9,120 for the year. In 2013, with the same drug now priced in the $50,000 range, if the Manufacturer Defendants covered all non-LIS and plan sponsor cost-sharing requirements ($13,800), each beneficiary would generate revenues four times higher of $36,200. Obviously, the economics returns for the Manufacturer Defendants for offsetting all cost-sharing requirements have escalated considerably with the massive Part D MS drug price inflation.

55. As discussed previously, escalating Reinsurance Subsidy payments for non-LIS Catastrophic drug costs have been largest contributing factor to Part D spending growth since the start of the program. Aggregate Part D Reinsurance payments increased from $6.0 billion in 2006 to $15.6 billion in 2012. See **Exhibit 5.** With CMS covering 80% of non-LIS Catastrophic spending, the CMS-reported Reinsurance Subsidies correspond to

$7.5 billion in Catastrophic Part D spending in 2006, rising to $19.6 billion in 2012. See **Exhibit 9.** At a 15% rate, the *"potential"* Part D plan sponsor annual cost-sharing burden from the accelerating Catastrophic spending has nearly tripled from $1.1 billion in 2006 to $2.9 billion in 2012.

56. To put the magnitude of this plan sponsor cost-sharing burden in perspective, the Part D plan bids for all sponsors across the nation in 2007 included *"expected profits"* of only $1.07 billion. *GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.* Cumulatively, non-LIS Part D Catastrophic spending and plan sponsor cost-sharing requirements approach $93 billion and $14 billion, respectively, in the first seven years of the Part D program. See **Exhibit 9.** In the Relator's view, there is no mathematical possibility that the PBM Defendants could handle these massive Catastrophic cost-sharing requirements without the majority being offset by drug manufacturers via excessive undisclosed FMV BFSFs or other fraudulent means.

57. Under the Part D regulations, plan sponsors are required to report *"any type of remuneration, such as discounts or rebates that affect the actual cost of the drugs paid by the sponsor." GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.* As such, if the Manufacturer Defendants were providing proper discounts or rebates to the PBM Defendants plan sponsor to offset their rising Catastrophic cost-sharing requirements, the payments would be reported to CMS as DIR and be reflected in restrained end-user Medicare Part D MS drug prices. The well-documented massive inflation of the Defendant MS drugs in Part D plans across the nation, as well as the stable modest level of rebates in the program (10-11% of overall program spending), clearly indicates that escalating plan sponsor cost-sharing requirement are not being offset in this manner.

58. While other forms of illegal payments are also possible, the Relator alleges that escalating fraudulent BFSFs has been the primary mechanism by which the Manufacturer Defendants offset the majority of the PBM Defendants' escalating Catastrophic cost exposure related to the collusive pricing scheme. First, the Manufacturer Defendants can pay the PBM Defendants an unlimited amount of BFSFs, with no direct government oversight or reporting requirements. Second, because BFSFs are excluded from "*negotiated price"* calculations, both Defendant parties benefit considerably by passing the full, massive price increases on to CMS and Part D beneficiaries.

59. Of note, CMS does not appear to require any direct reporting by the PBM Defendants regarding the financial accounting of their 15% cost-sharing responsibility for non-LIS beneficiaries in the Catastrophic phase. According to the Relator's review, once an individual non-LIS beneficiary crosses the annual Catastrophic threshold, the PBM Defendants simply report to CMS the *"gross drug cost paid to the pharmacy above the out-of-pocket threshold for a given Prescription Drug Event (PDE) for a covered drug."*

This data is reported in PDE field #31, entitled *Gross Drug Cost Above Out-of-Pocket Threshold (GDCA). CMS Prescription Drug Event Participant Guide, 2011 Regional IT Technical Assistance.* As pertains to the PBM Defendants, the opportunity for fraud in submitted PDE data, including GDCA, is considerable for several reasons. First, in virtually all instances in Part D, the plan sponsor, the PBM and the specialty pharmacy functions are provided by parties under the same ownership structure or by closely-affiliated entities. Second, CMS has admitted that it has no mechanism to routinely verify the accuracy of submitted PDE submitted by the PBM Defendants. *Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010*. The Relator expects discovery to uncover significant fraud by the PBM Defendants related to their non-LIS Catastrophic cost-sharing requirements, both in related party transactions and in remuneration from the Manufacturer Defendants. As a result of the collusive pricing scheme, the PBM Defendants have knowingly submitted a myriad of fraudulently price-inflated PDE *"claims for payment"* to CMS.

60. In Part D, risk sharing provisions require that the Federal government share in plan sponsor *"unexpected"* profits and losses. *42 U.S.C. § 1395w-115(e).* To determine whether risk-sharing payments are required by either the government or the plan sponsor, CMS compares the plan's *"target amount"* to the plans *"allowable costs"*. The *"target amount"* is the *"sum of the prospective Direct Subsidy payments and the beneficiary premiums, reduced prospective by the sponsor's administrative costs". GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.* Importantly, Direct Subsidy payments and beneficiary premiums are based upon plan sponsor bids, which also include *"expected profits"* for the Part D plan year. The plan's *"allowable costs"* include actual covered Part D drug costs incurred minus *"Direct and Indirect Remuneration"* (DIR) and Reinsurance Subsidy payments. The difference between the *"target amount"* and the *"allowable costs*" is the Part D plans *"unexpected"* profit or loss.

61. CMS has established *"Risk Corridors"* in order to determine required payments for either the government or plan sponsors related to *"unexpected"* profits or losses. For profits or losses less than or equal to 5% of the *"expected profit"*, the plan sponsor bears the full additional benefit or cost. For profits or losses greater than 5% but less or equal to 10% of the *"expected profit"*, the plan sponsor and the government split the additional benefit or cost equally. For profits or losses greater than 10% of the *"expected profit"*, the plan retains only 20% of the additional profit and only covers 20% of the additional losses.

62. Since the Reconciliation Subsidy payments are included in *"allowable"* costs for *"Risk Corridor"* calculations, the plan sponsors actually share risk with the government regarding excessive non-LIS beneficiary Catastrophic spending associated with the massive Manufacturer Defendants MS drug price inflation. However, the financial risk to the PBM Defendants appears very modest. First, in the reconciliation process, CMS will reimburse the plan sponsor for 80% of unlimited excess Catastrophic spending during the

plan year. As such, a plan sponsor only faces potential financial risk for its 15% cost-sharing portion of the cost over-runs. Second, the *"Risk Corridors"* only pertain to *"unexpected profits"*, not plan profits anticipated in annual sponsor bids. As such, the PBM Defendants do not have a real risk of significant losses unless the plan sponsor wildly underestimates Catastrophic Subsidy payments in the plan bid. Even in such an extreme case, CMS will cover 80% of the additional costs for the plan year. In the case of under-estimated Catastrophic drug costs, the PBM Defendants gets to keep the majority of the excess gains unless plan profits exceed the *"target amount"* by more than 10%. In any case, the Relator considers any potential PBM Defendants Catastrophic risk to be largely mute, since drug manufacturers are no doubt covering the majority of the costs. Furthermore, as noted previously, the PBM Defendants bear no risk for in the LIS Subsidy population since CMS covers virtually all drug costs for these beneficiaries.

63. As part of the 2003 MMA legislation, the drug benefit for many of the highest cost, most-severely ill beneficiaries *"dual eligibles"* beneficiaries were forcibly switched, without recourse, from state Medicaid programs to Medicare Part D. *"Dual eligibles"* are low-income elderly and disabled beneficiaries eligible for both Medicaid and Medicare benefits. Former State *"dual eligibles"* account for the majority (63-70% each program year thus far) of Part D LIS beneficiaries which, in turn, account for the majority of Part D *"specialty drug"* spending, including the Manufacturer Defendants MS drugs. See **Exhibit 10**. By law, each State is required to fund a significant portion of Medicare Part D spending for their respective *"dual eligible"* beneficiaries via *"phased-down contribution"* or *"clawback"* payments to CMS paid on a monthly basis. In the program years 2006 through 2013, State *"clawback"* payments accounted for 32-37% of Part D LIS Subsidy costs each year. See **Exhibit 10**. Furthermore, the State Part D financial responsibilities are legally tied to Federal Medicaid matching transfers. As such, if any State fails or refuses to pay its CMS-determined *"clawback"* payments, the same amount will be deducted from its scheduled Federal Medicaid matching funds.

64. In May 2013, the Relator obtained *"confidential"* data regarding the pricing of Defendant Biogen's Avonex, Defendant Teva's Copaxone and Defendant Bayer's Betaseron in the Medicaid and 340B programs. The 340B program was created in 1992 to provide discounts equal to Medicaid on outpatient prescription drugs to select low-income patients via safety net providers. As indicated in **Exhibit 11**, in Medicaid, all three Manufacturer Defendant drugs are available at an 80-99% discount to the Average Wholesaler Price (AWP), representing an extreme discount to pricing in Medicare Part D. This massive cost discrepancy has occurred because the Medicaid/340B legislation has prevented manufacturers from benefiting from price increases beyond CPI-U *("Consumer Price Index - Urban")* since 1991-1992. As such, with the non-recourse transfer of State *"dual-eligibles"* to Medicare Part D, the government cost for the Manufacturer Defendants MS drugs in all 50 States has been greatly escalated by the fraudulent pricing scheme outlined in this complaint. As such, with this First Amended Complaint, the Relator is adding the 29 States with False Claims Act Statutes (plus the District of Columbia) as plaintiffs against the Manufacturer and PBM Defendants in this Qui Tam case.

65. Overall, States made cumulative *"clawback"* payments to CMS of $46.6 billion for the years 2006 through 2012. State *"clawback"* payments would have been considerably higher but for Federal relief ($4.3 billion in 2010 plus additional funds in the first half of 2011) as part of the American Recovery and Reinvestment Act of 2009 ("ARRA"). Actual reported State annual *"clawback"* payments increase from $5.5 billion in 2006 to $8.4 billion in 2012, up 53% in line with overall LIS spending growth. See **Exhibit 10**.

66. Of note, the amount of fraud in separate States related to this collusive pricing scheme will vary considerably due a number of key factors. First, individual State *"clawback"* payments are directly tied to the number of *"dual eligibles"* which varies considerably by State. For instance, California and New York have the greatest number of *"dual eligibles"* by a wide margin. In 2008, California and New York reported approximately 1.2 million and 737,000 *"dual eligibles*", respectively, accounting for 13.1% and 8.1% of the approximately 9.1 *"dual eligibles*" nationwide. See **Exhibit 12**. *Kaiser Family Foundation Issue Brief, "Medicare Role for Dual Eligible Beneficiaries", April 2012.* Furthermore, the top ten states by *"dual eligible"* enrollment (in size order in 2008: California, New York, Texas, Florida, Pennsylvania, Illinois, North Carolina, Ohio, Tennessee and Michigan) accounted for more than 5 million or 55% of nationwide *"dual eligibles"*.

67. Second, States are also responsible for varying percentages of *"dual eligible"* Part D drug spending, i.e., each State's Federal Medical Assistance Percentage (FMAP) used in *"clawback"* calculations. States with lower average income levels receive higher levels of Federal assistance. For instance, on the high end Mississippi's FMAP for calendar year 2013 was 72.04 vs. 50.00 (the minimum FMAP rate) for numerous larger States (California, New York, Illinois, etc.) Third, the Part D legislation *"phases down"* all State payments from 90% of their respective share in 2006 to 75% in 2015 and beyond.

68. Finally, the use of the Manufacturer Defendants MS drugs could also vary considerably by State since MS typically starts at a younger age (typically diagnosed between age 20 and 50 years old). While CMS does not seem to disclose specific diagnosis data for the *"dual eligible"*/LIS population, the Relator found reference indicating that the prevalence of MS in younger, disabled *"dual eligibles*" is approximately three times higher compared to those over 65 years old (6% vs. 2%). *Partial Profiles of the Dual Eligible Population in King County and Snohomish Counties, 2010, Washington State*. As such, States with a greater proportion of younger disabled *"dual eligibles"* will likely have greater Manufacturer Defendants MS drug use. While disabled, under 65 year-old beneficiaries accounted for 39% of all *"dual eligibles"* nationally in 2008, the variation by State is considerable. At the high end, 60% of *"dual eligibles"* in 2008 in New Hampshire were younger disabled beneficiaries; at the low end, only 23% in Massachusetts fell into this category. See **Exhibit 13**. However, regardless of State variations, the financial fraud related to the Manufacturer Defendants MS

drugs has no doubt been considerable in all States given the magnitude of the price inflation in Part D and significantly lower Medicaid prices.

69. The Relator has determined that the majority of the alleged fraud has occurred in the Low-Income Subsidy and Reinsurance Subsidy payments in the Part D program. As such, the amount and nature of the fraud for individual PBM Defendants will vary with the enrollment characteristics of the Part D plans for which they serve as sponsors and/or PBM contractors. For instance, PBM Defendants with high LIS and non-LIS enrollment, respectively, will have corresponding greater MS drug fraud in LIS Subsidy and Re-insurance Subsidy payments, respectively.

70. In **Exhibit 14**, the top five Medicare Part D PDP plans by LIS and non-LIS enrollment are provided for 2013. *Kaiser Family Foundation, Issue Brief, Medicare Part D Prescription Drug Plans: The Marketplace in 2013 and Key Trends, 2006-2013, December 2013.* As indicated, the CVS Caremark-sponsored SilverScript Basic plan has by far the largest PDP LIS enrollment, with 2.6 million beneficiaries and a 31.6% share of all US LIS Part D enrollees in 2013. In descending order, the next four largest PDPs by LIS enrollment in 2013 were sponsored by Humana, United Healthcare, Cigna (with a PBM partnership with Catamaran) and Wellcare; overall the top five Part D PDP plans accounted for 64.2% of all US LIS Part D PDP enrollment in 2013.

71. The US non-LIS Part D enrollment is even more concentrated. In 2013, the United Healthcare/AARP MedicareRx Preferred plan had 3.1 million non-LIS enrollees, accounting for 31.9% of nationwide non-LIS part D PDP enrollment. In addition, the next two largest plans are both sponsored by Humana, with combined non-LIS enrollment of about 2 million, representing approximately 20% of national non-LIS PDP enrollment. As such, two organizations control more than 50% of the PDP non-LIS enrollment. Overall the top five plan concentration of the non-LIS PDP market (62.6%) is similar to that for the LIS PDP market. See **Exhibit 14**.

72. In 2013, stand-alone PDP plans accounted for 63% of Part D enrollment in 2013, with Medicare Advantage-PD plans accounting for the remaining 37%. In 2012, 83% of Medicare Advantage insurance plans included Part D drug coverage. However, the distinction between PDP vs. Medicare-PD is irrelevant to the fraud in this case, since both types of Part D plans are governed by the exact same statutes, as per the *Code of Federal Regulations* and the *Medicare Prescription Drug Manual*. Although the Relator had not been able to locate similar recent details of LIS and non-LIS enrollment in Medicare Advantage-PD plans, the market is also quite concentrated. For instance, in 2012, United Healthcare, Humana and Blue Cross/Blue Shield plans (with PBM services provided in partnership with Express Scripts) accounted for more than 53% of US Medicare Advantage enrollment. See **Exhibit 15**.

73. With considerable industry consolidation (of the Managed Care, PBM and specialty pharmacy industries) both before and after the 2006 enactment of the MMA legislation, the Part D program has been dominated by integrated sponsor/PBM/specialty pharmacy organizations since the start of the program. PBM Defendants United Healthcare, Humana, Wellcare, Express Scripts and CVS Caremark have full ownership of the PBMs/specialty pharmacies servicing the plans for which they serve as sponsors. In addition, exclusive partnerships among the PBM Defendants have further increased the concentration of the PBM function within Medicare Part D. In plans sponsored by Aetna, Cigna and Wellpoint, pharmacy benefits are provided via ill-defined long-term contracts with the PBMs CVS Caremark, Catamaran and Express Scripts, respectively. However, corporate Security and Exchange Commission (SEC) filings indicate that Aetna, Cigna and Wellpoint have all maintained a significant amount of control over PBM functions for their Part D plans. In the Relator's view, close scrutiny of the terms and transactions related to these secretive PBM partnerships will be a key part of case discovery.

74. With these dynamics, the PBM Defendants have controlled more than 70% of overall Part D enrollment since the start of the program. In recent years, the Part D concentration of the PBM/specialty pharmacy functions has further increased due to ongoing consolidation and growth by the dominant players. See **Exhibit 16**. In the PDP market, the top three PBMs, CVS Caremark, UnitedHealth Group and Express Scripts, controlled 64% of overall US enrollment in 2012. The top six PBMs, including most of the PBM Defendants, controlled 90% of US PDP enrollment in 2012. The concentration in the Medicare Advantage-PD market is modestly lower. The top three PBMs, UnitedHealth Group, Express Scripts and Humana, controlled 56% of US enrollment in 2012. The top six PBMs controlled 63% of Medicare Advantage-PD enrollment in 2012. Combining Part D and Medicare Advantage-PD, the top six PBMs controlled at least 79% of overall US Part D enrollment in 2012. The PBM Defendants likely have additional service contracts with smaller Part D plan sponsors, as well.

75. Based upon the largest US PBM's (Express Scripts) own public data, the Relator has determined that the MS therapeutic category has been the largest driver of specialty and overall drug spending growth in Medicare Part D in recent years. The dominant growth role of the MS category has been due to the collusive pricing of the Manufacturer Defendants' MS drugs, as well as the outpatient nature of drug therapy in multiple sclerosis. Because most MS drugs, including all of the Manufacturer Defendants' therapies, are self-administered at home, more than 90% of MS drugs are distributed through the *"pharmacy benefit"*, (i.e., Medicare Part D for elderly and disabled beneficiaries). *Express Scripts 2011 Drug Trends Report.* In sharp contrast, although cancer drugs account for the greatest amount of overall specialty drug spending for elderly beneficiaries, most of these treatments (78%) are administered via a patient's *"medical benefit"* under Medicare Part B in the hospital, clinic or a physician's office. See **Exhibit 17**.

76. Adjusting for Part D usage, according to Express Script's data, the MS category has accounting for the greatest portion of Part D specialty drug spending, by a wide margin, for the past three years. As per **Exhibit 18**, the MS category accounted for approximately 28%, 44% and 39% of Part D specialty drug spending growth in 2011, 2012 and 2013, respectively. *Express Scripts Drug Trends Reports, 2010-2013.* The contribution from the two other largest specialty drug categories, cancer and inflammatory therapies, has been for more modest. Cancer therapies accounted for 19%, 17% and 13% of Part d specialty drug growth in 2011, 2012 and 2013, respectively. Inflammatory therapies (rheumatoid arthritis, psoriasis, etc.) accounted for 14%, 17% and 14% of Part d specialty drug spending growth in 2011, 2012 and 2013, respectively. See **Exhibit 18**. *Express Scripts Drug Trends Reports, 2010-2013.*

77. With growth driven primarily by fraudulent price inflation, the MS category's share of overall Part D specialty drug spending has risen sharply in recent years, from 17% in 2010 to 29.3% in 2013, according to Express Script's data . By comparison, the cancer therapy share of Part D specialty drug spending rose from 10% in 2010 to 13% in 2013. The inflammatory therapy share of Part D specialty drug spending decreased from 18% in 2010 to 16% in 2013. See **Exhibit 19**. *Express Scripts Drug Trends Reports, 2010-2013.*

78. Although the MS specialty drug category has been to largest driver of Medicare Part D drug spending, the Relator suspects that Express Scripts may actually be under-reporting the severe impact of the massive price inflation for the Manufacturer Defendants MS drugs. First, in the *"Top 10 Medicare Specialty Therapy Classes"* list, Express Scripts claims that increased utilization has contributed significantly to Medicare MS spending growth each year from 2010 through 2013. *Express Scripts Drug Trends Reports, 2010-2013.* More specifically, Express Scripts claims that increased MS drug *"utilization"* added 10%, 20%, 9% and 6% to Medicare MS drug spending growth in its client base for 2010, 2011, 2012 and 2013, respectively. See **Exhibit 20**. However, Express Script's claim of a strong increase in Part D MS drug utilization is inconsistent with the meager prescription growth trends in the mature US MS category. According to reliable IMS Health data, total US MS prescription growth has only averaged 0-2% year-over-year since the start of Medicare Part D. While two new oral US MS drugs (Novartis's Gilenya and Biogen's Tecfidara) have grown strongly in recent years, almost all of their gains have come at the expense of the eroding older Manufacturer Defendants MS drugs in a mature market.

79. The trends reported by Express Scripts for several of the key Manufacturer Defendants MS drugs for 2013 also do not appear reliable. Express claims that spending on Avonex in its clientele grew by 12.0% in 2013, with a 13.0% contribution from unit cost and -1.0% decline in utilization. Regarding Teva, Express Scripts claims that the use of Copaxone rose 11.4% in 2013, with a 12.1% contribution from unit cost and a -0.7% decline in utilization. *Express Scripts 2013 Drug Trends Reports.* Verifiable public data (pricing databases, IMS prescription data) clearly indicates far greater price increases in 2013 for both Avonex and

Copaxone, as well as a far sharper deterioration in patient usage. According to reliable IMS data, the US prescriptions for Avonex and Copaxone have been declining approximately -30% and -10% year-over-year, respectively, in 2013 due to severe new drug competition in the MS space. *IMS Health.*

80. Finally, the recent overall Express Scripts Medicare MS drug cost trends described above appear to be far below the company's own reported Per-Member-Per-Year (PMPY) spending amounts, as disclosed on the same page of the Drug Trends Report each year. Notably, as indicated in **Exhibit 20**, the Medicare MS drug *"trend"* and the PMPY increase match exactly at 34% growth for 2011. However, for unclear reasons, the reported Medicare MS *"trend"* is less than half the PMPY increase for both 2012 and 2013. For 2012, Express Scripts reported a 26.7% Medicare MS drug *"trend"* increase, but the PMPY amount calculates to a 61% year-over-year increase. Similarly, for 2013, Express Scripts reported a 19.8% Medicare MS drug *"trend"* increase, but the PMPY amount calculates to a 65% year-over-year increase. As proprietary data, the information provided in the Express Scripts Drug Trend Reports is not independently verifiable. The accuracy of the data can only be validated in discovery.

81. Since the 2006 start of Medicare Part D, due to severe new MS drug competition, the number of US patients treated with the Manufacturer Defendants' MS drugs has declined significantly. As such, in a non-collusive market environment, the oligopolistic negotiating leverage of the PBM Defendants would have prevented virtually all of the massive US price inflation (or perhaps caused price erosion) for the Manufacturer Defendants' MS drugs in the initial seven years of the Part D program. Without BFSF fraud and related price collusion, the US sales of the Manufacturer Defendants' MS drugs in Medicare Part D would have declined significantly between 2006 and 2013, leading rightfully to significant drug cost savings for CMS, elderly beneficiaries and general taxpayers. The sales/profits related to the Manufacturer Defendants' MS drugs would have rightly declined, along with legitimate patient/usage based BFSF payments to the PBM Defendants.

82. The US revenue and profit erosion would have been most detrimental for Manufacturer Defendants Biogen and Teva, since their respective MS drugs, Avonex and Copaxone, have accounted for the majority of US revenue and/or profits each year since the start of Medicare Part D. According its 10K filings with the Security and Exchange Commission (SEC), Avonex has accounted for 56-62% of US revenues each year from 2006 to 2012. *Biogen 10K filings with SEC.* Teva has also disclosed that Copaxone accounts for approximately 50% of worldwide corporate profits. *Steven Scheer, Reuters, August 1, 2013.* However, the US MS market is obviously the key driving factor for the Copaxone franchise, given the isolated massive domestic price inflation in recent years. In 2013, Teva reported worldwide Copaxone sales of $4.3 billion, with $3.2 billion or 75% in the United States. Unfortunately, rather than allow normal competitive forces to operate, the Manufacturer and PBM Defendants have knowingly entered into a

collusive arrangement to grow revenues and profits via utilizing fraudulent BFSFs tied to service contracts incorporating massive US MS drug price inflation.

83. The Relator views a corporate disclosure from PBM Defendant Wellcare in its 2013 10K on file with the Securities and Exchange Commission (SEC) as particularly incriminating. In the filing, Wellcare states: *"Historically, we have NOT experienced material adjustments related to CMS annual reconciliation of prior year low-income cost sharing, catastrophic reinsurance subsidies and coverage gap subsidies."* While seemingly innocuous, this statement suggests significant collusion between Wellcare and specialty drug manufacturers, especially regarding the Manufacturer Defendants' MS therapies in this case. Medicare Part D requires plan sponsors to submit plan bids six months prior to the effective date of the subsequent calendar plan year. In addition, as stated in the Humana 2013 10K*: "Settlement of the reinsurance and low-income cost subsidies as well as the risk corridor payment (for the "Regular Subsidy") is based on a reconciliation made approximately 9 months after the close of the year. This reconciliation process requires us to submit claims data necessary for CMS to administer the program."* Given the massive price increases since 2006 (often with multiple price increases in a single year) for the Manufacturer Defendants MS drugs, Wellcare's statement clearly indicates that the PBM Defendant has been consistently able to *"plan"* for these severe price increases. In a properly operating competitive market, accurate bid forecasting would be particularly essential for non-LIS Catastrophic spending since plans sponsor are responsible for 15% of excess costs beyond bid-based monthly Reinsurance Subsidy payments. Given that there is no rational basis for severe price increases for the declining Manufacturer Defendants drugs in the increasingly competitive US MS category since 2006, this disclosure by Wellcare clearly indicates potential collusive behavior that needs to be investigated aggressively. Furthermore, if a small Part D plan sponsor like Wellcare (only 4.4% and 1.1% of PDP and MA-PD enrollment in 2012) has such remarkable *"visibility"* on pricing trends in the top-spending MS drug category and other specialty drugs, one can be assured that the larger PBM Defendants have equal or better intelligence.

84. The severe impact in the US marketplace of this collusive scheme centered on the enactment of the Medicare Part D program is illustrated by a comparison of the domestic and international pricing trends of the Manufacturer Defendants MS drugs before and after 2006. Most noteworthy, PBMs are virtually non-existent in Europe while they control more than 80% of the US drug distribution market, including Medicare Part D. From the late 1990's until 2006, the cost of the four long-marketed Manufacturer Defendants MS therapies (Biogen's Avonex, Teva's Copaxone, Serono/Pfizer's Rebif and Bayer's Betaseron) were nearly identical in the US and Europe. However, since the start of Medicare Part D, the cost per patient in Europe has remained relatively stable in the $15,000 range while prices for the identical drugs in the US have soared in lock-step. See **Exhibit 21**. This widening disparity in geographic pricing is particularly hard to understand because MS drug volume growth remains far more robust overseas. Several of the Manufacturer Defendants have disclosed that increased European government pressure has caused some international MS drug price erosion

in recent years. As such, varying healthcare systems may explain some geographic price differences. However, the Relator alleges that collusion between the Manufacturer Defendants and the uniquely-American, oligopolistic PBM Defendants, driven by BFSF FMV fraud in the Medicare Part D program, is the primary cause of the widening geographic cost gap for the identical MS drugs.

85. The cornerstone of this complaint pertains to the handling in Medicare Part D of *"Bona Fide Service Fees"* (BFSFs), a minimally-discussed, yet highly impactful part of the CMS legislation. When the Medicare Part D legislation was enacted in 2003, CMS and legislators expected negotiated manufacturer rebates to be the primary method to both control program drug costs and to compensate Service Vendors (primarily PBMs and their wholly-owned specialty pharmacy subsidiaries in Medicare Part D) for their services in the Part D program. However, separately the CMS regulations governing Medicare Part D also allows manufacturers, via designated BFSFs, to compensate PBMs, specialty pharmacies and other Service Vendors for a wide array of product-related *"services"*, such as inventory management, patient education, phone support, shipping, reimbursement assistance, data reports, etc.

86. Due to the unique legislative handling of BFSFs in Medicare Part D, both the Manufacturer and PBM Defendants have a strong financial incentive to utilize BFSFs, rather than traditional discounts/rebates, as the preferred method for *"service"* compensation. By law, all negotiated manufacturer rebates/discounts/price concessions, whether passed through to the plan sponsor or retained by the PBM/specialty pharmacies or other Service Vendors, are reported to CMS as cost savings. CMS utilizes these manufacturer rebates/price concessions to lower drug price reimbursement levels, to lower Part D drug spending and to lower future beneficiary Part D premiums. As such, manufacturer compensation to PBMs and other intermediaries via traditional rebates/discounts leads to lower Part D end-user drug prices, leading to lower industry revenues and profits. In sharp contrast, BFSFs are excluded from government *"negotiated price"* calculations, leading to higher drug reimbursement prices and greater industry revenues/profits. Furthermore, the Part D legislation provides manufacturers and PBMs with wide latitude regarding the use of BFSFs. First, CMS has left the determination of the *"bona fide"* appropriateness of *"itemized services*" up to industry, with minimal reporting requirements or government oversight. Second, CMS has not placed any dollar limits on the use of manufacturer BFSF payments to PBM, specialty pharmacies and other Service Vendors in Medicare Part D.

87. Until the 2009 Part D plan year, CMS apparently did not require any reporting of BFSFs to the federal government by drug manufacturers, Service Vendors or Part D plan sponsors. The direct reporting of BFSFs by drug manufacturers and Service Vendors (unless the latter acts as a Part D sponsor as well) remains absent to the present day. However, starting with the Medicare Part D 2009 plan year, CMS began increasing plan sponsor BFSF reporting and legal requirements in their annual Direct and Indirect

Remuneration (DIR) reports used for payment reconciliation. Most notably, starting with the 2010 Part D plan year, plan sponsors are required to report all BFSFs received from manufacturers to CMS. In the DIR document, CMS stated *"Any bona fide service fees that are received in connection with the Medicare Part D program and are not included in rebate administration fees must be reported in this column (i.e., column in the DIR entitled "All Other Bona Fide Service Fees") Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, June 6, 2011.*

88. Furthermore, starting with 2010, CMS increased the sponsor requirements for BFSF documentation and FMV assessment, stating: *"Part D sponsors must describe the services provided for any bona fide service fees that are not rebate administration fees and the allocation methodology used to determine this amount".* The document further states *"In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4".*

89. Finally, CMS added BFSF FMV documentation requirements to DIR requirements starting with plan year 2012, stating: *"Documentation of the fair market value analysis needs to be maintained by the sponsor."* As such, the Relator alleges that, in addition to the PDE claims fraud described previously, the PBM Defendants in their role as plan sponsors (with the exception of Catamaran) have likely also directly submitted fraudulent BFSF data to CMS starting with the 2010 plan year. If properly reported, the service fee value in excess of FMV would have been accounted for by CMS as price concessions/discounts, leading to lower drug program MS drug prices and costs.

90. Indicative of the unique nature of this investigation, Relator has never seen the term *"Bona fide Service Fees"* mentioned in the public domain by any of the Manufacturer or PBM Defendants, either in investor forums or in Security and Exchange Commission (SEC) filings. This fact is particularly noteworthy since both the Relator's investigation, as well as first hand manufacturer/industry consultant commentary discussed later in the complaint, has determined that BFSFs have become the primary method of Service Vendor compensation from manufacturers in Medicare Part D.

91. Bases upon his investigation, the Relator concluded that the alleged Medicare Part D fraud outlined in this complaint is among the most well-orchestrated, multi-factorial corporate frauds ever perpetrated upon Federal/State governments, CMS and American taxpayers. Many factors contribute to both facilitating the fraud and enabling it to remain undetected prior to this complaint. While most of these factors are discussed in detail later in this complaint, a summary may help both the Court and Federal authorities to appreciate the systemic nature of the alleged fraud. **A Summary of Key Factors:**

The Highly Industry-Favorable Part D Legislation/Regulations:

- Federal drug price negotiations are legally prohibited in Part D.
- Unlike other Federal drug programs, no Part D protections against drug price increases.
- No restrictions on related Part D plan sponsor/PBM/specialty pharmacy ownership.
- Unlimited use of minimally-discussed *"Bona Fide Service Fees" ("BFSFs"*), which are excluded from *"negotiated price"* calculations, by drug manufacturers to compensate PBMs/specialty pharmacies in Medicare Part D.
- Late legislative transfer of high specialty drug-consuming *"dual eligibles"* from State Medicaid drug programs to Medicare Part D, with no opt-out provision for States.
- Federal government/State governments/taxpayers, not drug manufacturers or plan sponsors/PBMs, bear virtually all the drug costs for Low-Income Subsidy (LIS) Part D beneficiaries, including escalating spending due to severe price increases.
- Federal government/State governments/taxpayers bear the majority (80%) of Catastrophic drugs costs for non-LIS Part D beneficiaries, including escalating spending due to severe price increases.
- Highly industry-favorable Part D formulary guidelines/regulations, especially regarding specialty drugs.
- Minimal CMS regulation/oversight of both manufacturer and independent Patient Assistance Programs (PAPs) despite significant Federal fraud concerns.

Part D Reporting/Disclosure/Compliance Limits Detection of the Alleged Fraud:

- No direct CMS reporting requirements regarding BFSFs for drug manufacturers and PBMs throughout history of the Part D program; Plan sponsor BFSF reporting requirements only starting in 2010.
- No direct CMS documentation requirements regarding *"itemized"* bona fide services provided by PBMs/specialty pharmacies for manufacturers.
- No direct CMS documentations requirements for manufacturer FMV BFSF determinations/methodologies.
- No direct CMS reporting requirements regarding actual PBM drug prices paid to drug manufacturers.
- No scheduled CMS audits of drug manufacturers or PBM in Medicare Part D.
- No CMS mechanism to verify accuracy of Prescription Drug Event ("PDE") data submitted by plan sponsors and PBMs.
- Limited access to Prescription Drug Event (PDE) data (especially cost items) outside CMS; limiting capabilities of key Federal, State and private fraud detection organizations.

- Part D fraud compliance programs for plan sponsors and PBM contractors are self-administered; no CMS mechanism to ensure compliance prior to fraud allegations, such as Qui Tam cases.
- Minimal CMS disclosure requirements for manufacturer-funded Patient Assistance Programs (PAPs).

Additional Factors:

- Federal government/State governments/taxpayers pay for virtually all drugs costs for Part D Low-Income Subsidy beneficiaries (70% of specialty drugs); thus, no LIS beneficiary price sensitivity/awareness.
- Vast escalation of manufacturer-funded Patient Assistance Programs (PAPs) to cover escalating non-LIS Part D beneficiary out-of-pocket costs associated with massive specialty drug price inflation; thus, decreased non-LIS beneficiary price sensitivity/awareness.
- CMS inclusion of all manufacturer-funded PAP contributions in beneficiary annual TrOOP (True-Out-Of-Pocket) amounts; accelerates price inflation incentive and hastens attainment of the annual *"Catastrophic"* spending limit after which CMS covers 80% of non-LIS drug costs.
- CMS inclusion of manufacturer 50% Gap Discount Subsidy in annual TrOOP amounts; accelerates price inflation incentive and hastens attainment of the annual *"Catastrophic"* spending limit.
- Dominant drug manufacturer funding of MS patient support organizations to deflect scrutiny from extreme MS drug price inflation.
- Finally, the initial over-estimation of Medicare Part D costs projections and early under-forecast spending (unrelated to Part D's execution) continues to allow industry and supportive constituencies to claim program success; Deflect scrutiny from the collusive price inflation of numerous specialty drugs.

92. As a long-standing professional healthcare analyst, the Relator is aware of the atypical nature of this Qui Tam filing. To date, the majority of major whistleblower cases targeting the pharmaceutical industry have been off-label marketing cases brought forward by true insiders. Similarly, the majority of PBM whistleblower cases have been brought forward by insiders or related individuals with direct transactional experience with defendants. In contrast, the Relator in this case is not an insider at any of the Defendants, but rather an industry expert who has filed this case based upon extensive expertise, investigation and supporting factual evidence. The information provided in this complaint provides substantive, particular, and in the Relator's view, overwhelming *"original source"* evidence of an extensive, national fraud of potentially

unprecedented magnitude. As listed above, many factors have contributed to the systemic fraud outlined in this case. However, the Relator has determined that the consistent regulatory and legal handling of *"Bona fide Service Fees"* in Medicare Part D provides a clear path for holding both the Manufacturer and PBM Defendants accountable for this fraudulent scheme.

93. The Relator expects Defendant challenges to these fraud allegations to center around three indisputable facts in this case. These three facts all relate to the Relator's status as an industry expert, not an insider, customer or related party to any of the Defendants named in the case.

a.) First, despite extensive effort, the Relator is not able to provide to the Court actual *"confidential"* service contracts (typically as a percent of sales, inclusive of price increases) between the Manufacturer and PBM Defendants. Undoubtedly, given potential fraud and liability implications, such contracts are closely guarded by both Defendant parties in this FCA action. However, the Relator believes that, via both investigation and first-hand industry feedback detailed in this complaint, he has provided definitive evidence of their existence.

b.) Second, the Relator is not able to provide to the Court actual transaction documents regarding either excessive FMV *"Bona Fide Service Fees"* (BFSFs) or remuneration for bogus service fees paid by the Manufacturer Defendants to the PBM Defendants. However, this fact should not be surprising to the Court since CMS has never required the reporting of BFSFs by drug manufacturers and PBM entities in Medicare Part D. In fact, in the Relator's view, the lack of disclosure responsibility, along with the *"unlimited"* amount of BFSF exclusion from *"negotiated price"* calculations, have been key factors enabling an alleged fraud of such severe magnitude and duration to go apparently undetected until the filing of this complaint. To the Relator, the staggering five-fold US price inflation for the Manufacturer Defendants MS drugs, despite a steep decline in patient usage, suggests that both parties in the fraudulent scheme may believe they are operating with impunity. Once again, based upon extensive investigation and analysis, the Relator believes he has provided definitive evidence of the payment of large amounts of fraudulent BFSFs far in excess of FMV from the Manufacturer Defendants to the PBM Defendants in Medicare Part D.

c.) Third, as an external expert, the Relator has not provided specific false claims submitted by the PBM Defendants in the form of *"Prescription Drug Event"* (PDE) data, which recent case precedent (*Spay v. CVS Caremark*) has clearly established as

"claims for payment" under the FCA. However, the well-documented severe price inflation for the Manufacturer Defendants MS drugs in Part D (from both CMS and PBM industry data) guarantees that a myriad of elevated PDE cost data has been submitted for reimbursement which is directly linked to the fraudulent *"negotiated prices"* determined mutually by the Defendant parties in this collusive scheme. Furthermore, as discussed in this complaint, PDE data is not available to the public, except in rare circumstances and only on a limited basis.

94. The Supreme Court has emphasized that *"only a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662 (2009*). *"Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id*. Furthermore, the court must *"accept all factual allegations in the complaint as true and view them in the light most favorable to the plaintiff." Buck v. Hampton Twp. Sch. Dist., 452 F. 3rd 256, 260 (3d Cir, 2006). The court must also "determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Pinkerton v. Roche Holdings Ltd., 292 F. 3d 361, 374 n.7 (3d Cir. 2002).* In addition, the *"complaint's allegations must be enough to raise a right of relief above the speculative level." (quoting Twombly, 550 U.S. at 555).* Finally, the Supreme Court has repeatedly explained that *"Congress wrote expansively"* in the FCA, with the intent *"'to reach all types of fraud without qualification that might result in financial loss to the Government." Cook County v. United States ex rel. Chandler, 538 U.S. 119, 129 (2003) (quoting United States v. Neifert-White Co., 390 U.S. 228.232 (1968)).* In the Relator's view, the extensive factual and investigative evidence provided in this complaint surpass the legal requirements to proceed to discovery by a wide margin. In fact, after his extensive investigation, the Relator has concluded that severe service fee-related fraud between the Manufacturer and PBM Defendants, driven by the *"hidden"* unique BFSF financial incentives in Part D, is the only *"plausible"* explanation for the massive US inflation of these older, largely-interchangeable MS drugs.

95. Qui Tam cases brought forward under the FCA must also be pled with *"particularity"* under the Federal Rule of Civil Procedure 9(b). The FCA imposes civil liability on any person who *"knowingly presents, or causes to present" to the government "a false or fraudulent claim for payment or approval."* 31 U.S.C. § 3729(a)(1). Thus, the fundamental elements of an FCA action are: (1) a person presents or caused to be presented a claim for payment to the Government or an agent of the government; (2) the claim is false or fraudulent; and (3) the person acted with actual knowledge of the information, or with deliberate ignorance or reckless disregard of the truth or falsity of the information. *United States. ex rel. Schmidt v. Zimmer. Inc. 386 F. 3rd 235, 242 (3'd Cir 2004).* The FCA does not define *"false or fraudulent."* Under Rule 9 (b), plaintiffs must *"plead with particularity the "circumstances" of the alleged*

fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). This standard requires a description of the *"who, what, when, where and how of the events at issue." In re Rockefeller Ctr. Props., Inc. Secs. Litig., 311 F. 3d 198, 217 (3d Cir. 2002).* Finally, Rule 9(b) is generally considered satisfied when a defendant has *"fair notice"* of the charges against it. *United States v. Kensington Hosp., 760 F. Supp. 1120, 1126 (E.D. Pa. 1991).* Once again, the Relator believes the extensive evidence provided in this Qui Tam filing exceeds the FCA particularity requirements by a wide margin. This complaint is very specific regarding the nature of the fraud, its estimated financial magnitude, as well as the transactional pathway for the false claims. The Relator alleges that the intentional fraudulent payment and non-disclosure to CMS of services fees far in excess of FMV by the Manufacturer Defendants *"caused"* the PBM Defendants to knowingly submit a myriad of *"false claim"* data (primarily in PDE reports) to the Federal government for payment. Based upon mutually determined service contracts linked to collusive price increases, both the Manufacturer and PBM Defendants knowingly participated in this fraudulent scheme that led to massive overpayment for MS drugs in the Part D program. In this complaint, the Relator has provided a vast amount of highly consistent factual and analytical evidence that all points to this same troubling conclusion.

JURISDICTION AND VENUE

96. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. 3730(e), there has been no statutorily relevant public disclosure of the *"allegations or transactions"* in this Complaint. Relator is the original source of the facts and information alleged in this Complaint.

97. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C.§3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in this District and /or transact business in this District.

98. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

PARTIES

99. Plaintiff/Relator John R. Borzilleri, MD ("Relator"), an investment fund manager and physician, is a resident of Cutchogue, New York. He has been a professional healthcare industry investment analyst for over two decades and has dedicated over 18 months in an extensive effort to identify the factors behind the extreme price inflation in the US specialty drug market for multiple sclerosis (MS) and other therapeutic areas. The Relator is a licensed physician in the State of New York.

100. Defendant Bayer AG ("Bayer") is headquartered in Berlin, Germany, with its U.S. headquarters at 340 Changebridge Road, Montville, NJ 07045-1000. Bayer is among the top 15 pharmaceutical companies worldwide and has about $15 billion in annual pharmaceutical revenues. Bayer focuses on Multiple Sclerosis, Cardiovascular, Women's Health, and Oncology. Related to this case, Bayer AG markets Betaseron in the United States for the treatment of multiple sclerosis.

101. Defendant Biogen Idec, Inc. ("Biogen") is a Delaware corporation, headquartered at 14 Cambridge Center, Cambridge MA 02142. Biogen discovers, develops, manufactures, and markets therapies in multiple sclerosis and other autoimmune diseases, neurodegenerative diseases and hemophilia. Biogen Idec sells its products in more than 90 countries and has about $6 billion in annual revenues. Related to this case, Biogen markets Avonex, Tysabri and Tecfidara in the United States for the treatment of multiple sclerosis.

102. Defendant Pfizer, Inc. ("Pfizer"), a Delaware corporation, is headquartered in New York City at 235 East 42nd Street, New York, New York 10017. Pfizer is the world's largest pharmaceutical company with a focus on cardiovascular/metabolic disease, immunology, inflammation and neuroscience. Pfizer sells its products throughout the world and has approximately $60 billion in annual revenues. Related to this case, Pfizer co-markets, with EMD Serono, Rebif in the United States for the treatment of multiple sclerosis.

103. Defendant EMD Serono, Inc. ("EMD Serono") is a biopharmaceutical subsidiary of Merck KGaA, a Darmstadt, Germany-based global pharmaceutical and chemical group. EMD Serono has more than 1,000 employees throughout the United States with fully integrated commercial, clinical and research operations near Boston and headquartered in Rockland, Massachusetts. EMD's key products include treatments for neurologic, fertility and metabolic disorders. The address of EMD Serono's US headquarters address is One Technology Place, Rockland, Massachusetts 02370. Related to this case, EMD Serono co-markets, with Pfizer, Rebif in the United States for the treatment of multiple sclerosis.

104. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva"), headquartered at 5 Basel St. Petach

Tikva 49131, Israel is a global leader in the development, manufacturing, and commercialization of generic and specialty drugs. Teva sells its products in 60 countries and has approximately $20 billion in annual revenues. Related to this case, Teva markets Copaxone in the United States for the treatment of multiple sclerosis.

105. Defendant Novartis AG is a multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of healthcare products led by innovative pharmaceuticals. Novartis AG, our Swiss holding company, owns, directly or indirectly, all of our significant operating companies. Key Novartis subsidiaries in the United States include Novartis Corporation and Novartis Pharmaceuticals Corporation, both based in East Hanover, New Jersey. Related to this complaint, Novartis markets Gilenya and Extavia in the United States for the treatment of multiple sclerosis. Novartis reported worldwide sales of $57.9 billion in 2013.

106. Defendants Bayer AG, Biogen Idec, Inc., Pfizer, Inc., EMD Serono, Inc., Teva Pharmaceutical Industries, Ltd. and Novartis AG are collectively identified as the "Manufacturer Defendants" in this complaint.

107. Defendant Express Scripts Holding Company ("Express Scripts"), headquartered in St. Louis, MO, and its subsidiaries, is the largest PBM company in the United States, offering a full range of services to our clients, which include managed care organizations, health insurers, third-party administrators, employers, union-sponsored benefit plans, workers' compensation plans and government health programs. Through our licensed insurance subsidiaries (i.e., Express Scripts Insurance Company ("ESIC"), Medco Containment Life Insurance Company and Medco Containment Insurance Company of New York), Express Scripts operates as Part D PDP sponsors offering PDP coverage and services to our clients and Part D beneficiaries. We also, through our core PBM business, provide Part D-related products and services to other PDP sponsors, MA-PDPs and other employers and clients offering Part D benefits to Part D eligible beneficiaries. Accredo Health Group and CuraScript Specialty Pharmacy, which is currently in the process of being rebranded ("Accredo®"), are focused on dispensing infused, injectable, inhaled and oral drugs that require a higher level of clinical services and support compared to what typically is available from traditional pharmacies. Express Scripts reported revenues and net income of $104 billion and $1.9 billion, respectively, in 2013.

108. Defendant CVS Caremark Corporation ("CVS Caremark"), headquartered in Woonsocket, RI, and its subsidiaries, is the largest integrated pharmacy health care provider in the United States. The Pharmacy Services Segment provides a full range of PBM services to our clients consisting primarily of employers, insurance companies, unions, government employee groups, managed care organizations ("MCOs") and other sponsors of health benefit plans and individuals throughout the United States. In addition, through our

SilverScript Insurance Company ("SilverScript") subsidiary, we are a national provider of drug benefits to eligible beneficiaries under the Federal Government's Medicare Part D program. The Pharmacy Services Segment operates under the CVS Caremark® Pharmacy Services, Caremark®, CVS Caremark®, CarePlus CVS/pharmacy®, RxAmerica®, Accordant®, SilverScript® and Novologix® names. CVS Caremark participates in the administration of the drug benefit added to the Medicare program under Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA, Medicare Part D") through the provision of PBM services to its health plan clients and other clients that have qualified as Medicare Part D prescription drug plans ("PDP"). CVS Caremark also participates (i) by offering Medicare Part D pharmacy benefits through our subsidiary, SilverScript, which has been approved as a PDP by the Centers for Medicare and Medicaid Services ("CMS"). CVS Caremark reported revenues and net income of $126.8 billion and $4.6 billion, respectively, in 2013.

109. Defendant Catamaran Corporation ("Catamaran"), headquartered in Schaumburg, Ill, and its subsidiaries, is a leading provider of pharmacy benefit management ("PBM") services and healthcare information technology ("HCIT") solutions to the healthcare benefit management industry. In addition, the Company is a national provider of drug benefits to its customers under the federal government's Medicare Part D program. On June 10, 2013, Cigna Corporation ("Cigna") announced that it had selected Catamaran to be its exclusive pharmacy benefit partner in a strategic 10-year agreement to service the more than 8 million Cigna members. The two organizations will partner on sourcing, fulfillment and clinical services. As a full-service PBM and a National Prescription Drug Plan, the Company supports a wide variety of Medicare Part D Plan Sponsors. The Company provides prescription benefit management support for Medicare Advantage Prescription Drug plans ("MAPDs") and prescription drug plans ("PDPs"), including implementation of specific Medicare Part D plan designs, creation and maintenance of Medicare Part D formularies (including CMS submission), CMS reporting requirements and consultative, proactive account management. Catamaran Corporation reported revenues and net income of $14.8 billion and $262.2 million, respectively, in 2013.

110. Defendant UnitedHealth Group, Inc., ("UnitedHealthcare") headquartered in Minnetonka, MN, and its subsidiaries, is a diversified health and well-being company. UnitedHealthcare provides health care benefits to a full spectrum of customers and markets. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits for Medicare beneficiaries and retirees. UnitedHealthcare Community & State manages health care benefit programs on behalf of state Medicaid and community programs and their participants. Optum is a health services business serving the broad health care marketplace, including payers, care providers, employers, government, life sciences companies and consumers, through its OptumHealth, OptumInsight and OptumRx businesses. UnitedHealthcare Medicare & Retirement provides Medicare Part D benefits to beneficiaries throughout the United States and its territories through its Medicare Advantage and stand-alone Medicare Part D plans. UnitedHealthcare Medicare & Retirement offers two standalone Medicare

Part D plans: the AARP Medicare Rx Preferred and the AARP Medicare Rx Saver plans. As of December 31, 2013, UnitedHealthcare had enrolled approximately 8 million people in the Medicare Part D program, including approximately 5 million individuals in the stand-alone Medicare Part D plans and approximately 3 million in its Medicare Advantage plans incorporating Medicare Part D coverage. UnitedHealth Group, Inc. reported revenues and net income of $122.5 billion and $5.7 billion, respectively, in 2013.

111. Defendant Humana, Inc. ("Humana"), headquartered in Louisville, KY, and its subsidiaries, is a leading health care company that offers a wide range of insurance products and health and wellness services. During 2013, 75% of Humana's total premiums and services revenue were derived from contracts with the federal government. Most Medicare Advantage plans offer the prescription drug benefit under Part D as part of the basic plan, subject to cost sharing and other limitations. At December 31, 2013, Humana provided health insurance coverage under CMS contracts to approximately 2,068,700 individual Medicare Advantage members. Humana offers stand-alone prescription drug plans, or PDPs, under Medicare Part D, including a PDP plan co-branded with Wal-Mart Stores, Inc., or the Humana-Walmart plan. Humana, Inc. reported revenues and net income of $41.3 billion and $1.2 billion, respectively, in 2013.

112. Defendant Wellpoint, Inc. ("Wellpoint"), and its subsidiaries, is one of the largest health benefits companies in terms of medical membership in the United States. Wellpoint is an independent licensee of the Blue Cross and Blue Shield Association, or BCBSA, an association of independent health benefit plans. Wellpoint serves its members as the Blue Cross licensee for California and as the Blue Cross and Blue Shield, or BCBS, licensee for: Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri (excluding 30 counties in the Kansas City area), Nevada, New Hampshire, New York (as BCBS in 10 New York city metropolitan and surrounding counties and as Blue Cross or BCBS in selected upstate counties only), Ohio, Virginia (excluding the Northern Virginia suburbs of Washington, D.C.), and Wisconsin. In a majority of these service areas Wellpoint does business as Anthem Blue Cross, Anthem Blue Cross and Blue Shield, Blue Cross and Blue Shield of Georgia, and Empire Blue Cross Blue Shield, or Empire Blue Cross (in our New York service areas). Wellpoint also conducts business through its AMERIGROUP Corporation, or Amerigroup, subsidiary in Florida, Georgia, Kansas, Louisiana, Maryland, Nevada, New Jersey, New York, Tennessee, Texas and Washington. Wellpoint offers a wide variety of senior plans, products and options such as Medicare supplement plans, Medicare Advantage and Medicare Part D Prescription Drug Plans, or Medicare Part D. Wellpoint markets and sells an integrated prescription drug product to both fully-insured and self-funded customers through our health benefit subsidiaries throughout the country. This comprehensive product includes features such as drug formularies, a pharmacy network and maintenance of a prescription drug database and mail order capabilities. Since December 1, 2009, Wellpoint has delegated certain functions and administrative services related to our integrated prescription drug products to Express Scripts under a ten year contract, excluding Amerigroup and certain self-insured members. Express Scripts manages the network of pharmacy

providers, operates mail order pharmacies and processes prescription drug claims on our behalf, while we sell and support the product for clients, make formulary decisions and set drug benefit design strategy and provide front line member support. Wellpoint reported revenues and net income of $70.2 billion and $2.5 billion, respectively, in 2013.

113. Defendant Cigna Corporation ("Cigna"), headquartered in Bloomfield, CT, and its subsidiaries, is a global health services provider of medical, dental, disability, life and accident insurance and related products and services. Cigna's Medicare Part D prescription drug program provides a number of plan options, as well as service and information support to Medicare and Medicaid eligible customers. Cigna's plans are available in all 50 states and the District of Columbia. With a network of over 65,000 contracted pharmacies, Cigna Pharmacy Management is a comprehensive pharmacy benefits manager ("PBM") offering clinical integration programs and specialty pharmacy solutions. Cigna Pharmacy Management also offers fast, cost-effective mail order, telephone and on-line pharmaceutical fulfillment services through our home delivery operation. Under a 2013 agreement, Catamaran Corporation provides Cigna with access to their technology and service platforms, prescription drug procurement and inventory management capabilities, retail network contracting and claims processing services. Cigna reported revenues and net income of $32.4 billion and $1.5 billion, respectively, in 2013.

114. Defendant Aetna, Inc. ("Aetna"), headquartered in Hartford, CT, and its subsidiaries, is one of the nation's leading diversified health care benefits companies. On May 7, 2013 (the “Effective Date”), Aetna acquired Coventry in a transaction valued at approximately $8.7 billion. The Coventry acquisition added medical membership, which increased Aetna's presence in government programs. Through annual contracts with CMS, Aetna offers HMO and PPO products for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna is also a national provider of the Medicare Part D Prescription Drug Program (“PDP”) in all 50 states and Washington, D.C. to both individuals and employer groups. Aetna offers pharmacy benefit management services and specialty and mail order pharmacy services to its members. Aetna's pharmacy fulfillment services are delivered by Aetna Specialty Pharmacy (“ASP”) and Aetna Rx Home Delivery®. ASP compounds and dispenses specialty medications and offers certain support services associated with specialty medications. In 2011, CVS Caremark began to perform the administration of selected functions for Aetna's retail pharmacy network contracting and claims administration; mail order and specialty pharmacy order fulfillment and inventory purchasing and management; and certain administrative services for Aetna. In addition, as a result of the Coventry acquisition, Express Scripts also provides certain pharmacy benefit management services to Aetna and our customers. Aetna, Inc. reported revenues and net income of $47.2 billion and $2.1 billion, respectively, in 2013.

115. Defendant Wellcare Health Plans, Inc. ("Wellcare"), headquartered in Tampa, FL, is a leading

managed care company for government-sponsored health care coverage with a focus on Medicaid and Medicare programs. According to the company, Wellcare is among the 10 largest Medicaid providers of managed care services plans, and among the ten largest providers of Medicare Advantage ("MA") plans and prescription drug plans ("PDPs"), all as measured by membership. As of December 31, 2013, Wellcare offered MA plans in a total of 204 counties across 14 states, with over 15 million eligible beneficiaries in these service areas. Wellcare has contracted with CMS to serve as a plan sponsor offering stand-alone Medicare Part D PDP plans to Medicare-eligible beneficiaries through our PDP segment. Wellcare's PDP plans offer national in-network prescription drug coverage with more than 60,000 pharmacies, including a preferred pharmacy network, subject to limitations in certain circumstances. Wellcare offers PDP plans in 49 states and the District of Columbia. Pharmacy services are reimbursed based on a fixed fee for dispensing medication and a separate payment for the ingredients. Wellcare Health Plans, Inc. reported revenues and net income of $9.5 billion and $175 million, respectively, in 2013.

116. Defendants Express Scripts Holding Company, CVS Caremark Corporation, Catamaran Corporation, UnitedHealth Group, Inc., Humana, Inc., Wellpoint, Inc., Cigna Corporation, Aetna, Inc. and Wellcare Health Plans, Inc. are collectively identified as the "PBM Defendants" in this complaint.

SUBSTANTIVE ALLEGATIONS

Background

117. The financial incentive for the Manufacturer and PBM Defendants to utilize BFSFs, rather than rebates/price concessions, is most severe in the Medicare Part D program due to its lack of legislative limits on drug price increases. By utilizing BFSFs for service compensation in Part D, both the Manufacturer and PBM Defendants can benefit significantly from severe drug price increases, leading to increased drug costs borne by CMS, elderly Part D beneficiaries and general taxpayers. In fact, the Relator has determined that the PBM Defendants have, in fact, received the vast majority of their compensation in Medicare Part D from the Manufacturer Defendants for services provided for their respective MS specialty drugs via fraudulent BFSFs since the 2006 start of the program.

118. CMS regulations require that all BFSFs in Medicare Part D be paid at *"Fair Market Value"* (FMV) commensurate with an *"arm's length"* transaction between unaffiliated parties, with drug manufacturers bearing the full legal responsibility for proper FMV assessment. Furthermore, by law, any fee amounts paid by the Manufacturer Defendants to the PBM Defendants in excess of FMV must be reported to CMS as price concessions which serve to lower drug costs in Medicare Part D. By willfully not reporting these excessive FMV BFSFs to CMS, the Manufacturer Defendants have caused the collusive PBM Defendants to submit

fraudulent Prescription Drug Event (PDE) as claims for payment to CMS for fraudulently elevated drug prices. In addition, since the 2010 Part D DIR reporting requirement changes, the PBM Defendants are likely reporting false BFSF data directly to CMS. Both Defendant parties are in clear violation of the CMS statutes governing Medicare Part D, as well as the Anti-Kickback Statute and the False Claims Act.

119. The Relator alleges that the Manufacturer and PBM Defendants have used the industry-favorable handling of BFSFs in Medicare Part D in a collusive pricing scheme for their mutual financial benefit that has led to fraudulent and excessive government drug costs. By using standard *"Market Approach/Percent of Revenue"* service fee contracts tied to collusive, massive price increases, the Relator alleges that the Defendant multiple sclerosis (MS) manufacturers/marketers have paid the Defendant PBMs (and/or their specialty pharmacy subsidiaries) in Medicare Part D excessive, fraudulent fees that bear no relation to the FMV of valid patient-based, "*bona fide"* services. Because these *"so-designated"* BFSFs have greatly escalated solely due to massive, near lock-step Manufacturer Defendants MS drug price increases in the face of a significant decline in patient usage, the Relator alleges the payments greatly exceed the FMV for appropriate compensation by a wide margin.

120. By law, fees in excess of FMV from manufacturers to Service Vendors are *"profit-sharing"* and *"payment for referral"*, in violation of the Anti-Kickback Statute. *American Lithotripsy Society v. Thompson, 215 F Supp. 2d 23 (200), US District Court, District of Columbia*. In addition, the fraudulent fees have led the PBM Defendants (in their role as both plan sponsors and PBM contractors) to submit fraudulently high cost and related data in PDE reports to CMS for reimbursement for the Manufacturer Defendants MS drugs, leading to significant overpayment by the Federal/State governments and Part D recipients. These actions are a clear violation of the False Claims Act.

121. While discovery will likely yield broad industry-wide evidence of BFSF FMV fraud in Medicare Part D, this complaint targets *"specialty"* (*i.e., high priced*) drugs for the treatment of multiple sclerosis, the therapeutic area which provides the clearest evidence of the fraud. Despite a significant decline in US patient usage for the Manufacturer Defendants' MS drugs (down an estimated 35-40% since the end of 2005) due to considerable competition from new drugs, the average annual US cost per patient for the Manufacturer Defendants' long-marketed MS drugs (Biogen's Avonex, Bayer's Betaseron, EMD Serono/Pfizer's Rebif and Teva's Copaxone) has risen five-fold since the start of Medicare Part D, from the $12,000 range at the end of 2005 to $50,000-60,000 per patient by year end 2013. Launched in the US in 2009, Novartis' Extavia's (identical drug to Bayer's Betaseron) initial price was in the $24,000 per patient per year range, but has risen to nearly $50,000 per patient in 2013. As discussed in this complaint, the Relator has determined that CMS and elderly beneficiaries have received only modest 10% or less manufacturer rebates off these rapidly inflating prices in each year of the Medicare Part D program since its inception. See **Exhibit 22**. As such, the

Manufacturer and PBM Defendants have reaped egregious financial profits from these massive price increases, with the cost burden primarily borne by CMS, elderly beneficiaries and general taxpayers.

122. Driven entirely by this massive price inflation, the combined US sales of the Manufacturer Defendant MS drugs have risen from approximately $2.5 billion in 2005 to the $7.1 billion range in 2013, counter to any *"plausible"* free-market rationale. See **Exhibit 3**. The disparity between patient usage and meteoric price-inflation fueled, revenue growth has been most extreme for Manufacturer Defendant Biogen's Avonex and Manufacturer Defendant Bayer's Betaseron. Despite an estimated 50% decrease in patient usage since the start of Medicare Part D, the US sales of Avonex increased from $939 million in 2005 to the $1.9 billion range in 2013, driven entirely by the massive price increases. With an even greater decline in US patient usage (estimated down 60-65% since 2005) and massive price inflation, US Betaseron sales have risen from approximately $370 million in 2005 to the $640 million range in 2013. With similar massive price increases, the US sales of Teva's Copaxone have risen from $782 million in 2005 to $3.2 billion in 2013, despite an estimated 15% decline in US patient usage. US sales of EMD Serono/Pfizer's Rebif have increased from about $390 million in 2005 to the $1.3 billion range in 2013, despite an estimated 25-30% decline in usage over the period. US sales of Novartis Extavia have been very modest, rising from less than the $10 million range in 2009 to only an estimated $35 million in 2013. Of note, Novartis does not report itemized sales for Extavia. The evidence of collusive price activity has been most severe over the past two years, especially in 2013, when all Manufacturer Defendants MS drugs have seen an accelerating decline in US patient use due to severe new drug competition. By the Relator's estimation, despite a 24% decline in patient usage just since the start of 2012, the average US price of the Manufacturer Defendants MS drugs has increased about 43% from about $41,000 per patient per year in January 2012 (before discounts/rebates) to about $58,500 in December 2013. See **Exhibit 1**.

123. A review of case history indicates that the financial magnitude of the alleged fraud in this complaint appears to be among the largest ever perpetrated by the biopharmaceutical industry. The Relator alleges that fraudulent FMV BFSF payments from the Manufacturer Defendants to the PBM Defendants have has been the primary factor leading to severe collusive pricing in the US MS marketplace. Furthermore, based upon his analytic expertise and clinical knowledge, the Relator alleges that a normal functioning competitive manufacturer/PBM marketplace would have prevented virtually all of the US price inflation that has occurred since the 2006 start of Medicare Part D for the Manufacturer Defendants MS drugs, given their declining volume trends due to severe new MS drug competition. Without the massive fraudulent price increases, the US sales of the Manufacturer Defendants MS drugs would have declined from the $2.5 billion range in 2005 to about $1.4 billion in 2013, based on an approximate 40-45% decline in patient usage over the same time frame. See **Exhibit 3**. As mentioned previously, based upon the PBM Express Scripts own data, the Relator has determined that price increases for the Manufacturer Defendants' MS drugs have been largest contributing

factor to specialty drug growth in Medicare Part D in recent years, accounting for an estimated 28%, 44% and 38% of overall spending growth in 2011, 2012 and 2013, respectively. See **Exhibit 18.** While Express Scripts only began disclosing specific Medicare spending data in 2010, the MS category has undoubtedly been a key growth driver in Part D since the start of the program, with severe price inflation of the Manufacturer Defendants MS drugs (which accounted for 100% of the US MS market in 2006) as the primary reason.

124. With the massive US MS drug price increases, the MS categories share of overall Part D specialty drugs spending, according to the Express Scripts data, has increased from an estimated 17.1% in 2010 to 29.3% in 2013. See **Exhibit 19.** This massive MS price inflation has a particularly severe impact in Medicare Part D because 90% of MS drug prescriptions are administer through the *"pharmacy benefit"* (i.e., Part D) since the Manufacturer Defendants products are injectables that are self-administered at home. In contrast, regarding the two other largest Part D specialty drug categories, only 22% of cancer therapies and 67% of inflammatory therapies are administered via Part D. See **Exhibit 17.** Because the onset of multiple is typically in young adulthood (most diagnosed between 20 and 50 years old, with the average MS patient around 40 years old), as expected, the MS drug category accounts for a greater proportion of specialty drug spending in the commercial insurance population (32.7% in the Express Scripts data in 2013). See **Exhibit 19**. However, noteworthy to the Relator, in contrast to the surging MS spending share in Part D since 2010, the MS category share in the commercial market has actually declined modestly between 2010 and 2013. These trends suggest greater price inflation/collusion in the Part D MS marketplace in recent years.

125. Since virtually all price inflation for the Manufacturer Defendants MS drugs since 2006 has been due to collusion with the PBM Defendants, the Relator estimates $5.7 billion in excess MS drug spending in the entire US marketplace just in 2013 alone and more than $25 billion since the start of Medicare Part D. See **Exhibit 3**. Of note, these fraud estimates are for the combined commercial and Medicare Part D markets where pricing is determined by *"private competition"*. The Relator has removed an estimate of discounted MS drug sales (10% of Manufacturer Defendant US sales in 2006, falling to 7% in 2013) to Medicaid and other price-controlled government drug programs. Combining the Part D and commercial trends from the Express Scripts data, the Relator estimates that Part D MS drug spending accounted for 12.5% of overall US MS drug spending in 2010, with the share rising to 26.5% in 2013. See **Exhibit 23**. In quantifying the magnitude of the fraudulent Part D Manufacturer Defendant sales since the 2006 start of the program, the Relator estimates that Part D accounted for approximately 12% of overall *"private market"* US MS drug sales in 2006, which more than doubled to 25% in 2013. With these parameters, the Relator estimates Part D fraudulent Manufacturer Defendants sales of more than $4.5 billion between 2006 and 2013. Given the cumulative nature of the massive price inflation and the rising role of the MS category in Part D, the magnitude of fraudulent US sales for the Manufacturer Defendants MS drugs has greatly accelerated with each year of the Part D program, rising from an estimated $68 million in 2006 to a staggering $1.4 billion in 2013. See **Exhibit 3**.

126. The fraudulent price inflation for the Manufacturer Defendants MS drugs has also provided a fraudulently-elevated pricing plateau for new therapies that have reached the US market in recent years. For instance, Biogen's highly successful new oral MS therapy, Tecfidara, was initially priced at approximately $53,000/US patient in March 2013, which at the time represented a modest discount to the fraudulent price level of Biogen's long-marketed therapy, Avonex. Biogen recently reported first year US 2013 Tecfidara sales of $863 million. The Relator alleges that the fraudulent pricing plateau accounts for a significant portion of Tecfidara's US sales, although the fraud estimates in this case only include the older Manufacturer Defendants MS drugs. In addition, other recent new US MS drugs have also benefited from the severe price inflation in the category, including Novartis' Gilenya (2013 worldwide sales of $1.93 billion, up 62% over 2012) and Sanofi's Aubagio (2013 worldwide sales of approximately $230 million). Gilenya and Aubagio each now cost $54,000-60,000 per patient per year in the US. As will be discussed later, the Novartis' decision not to aggressively compete in the US market since 2009 with Extavia (minimal market impact despite being the identical molecule as Bayer's Betaseron) was likely in order to preserve pricing flexibility for Gilenya, its newer oral therapy which offered far greater sales potential.

127. Through his investigation, the Relator has determined that the vast majority of *"services"* provided to the Manufacturer Defendants by the PBM Defendants for the long-marketed MS drugs (all available in the US for at least 10 years) are standardized and based upon patient usage and drug volume. As such, both drug industry *"insider"* FMV experts, as well as external FMV consultants serving drug manufacturers/marketers, recommend that the straightforward *"Cost Approach"* be employed in determining the FMV of so-called *"Bona Fide Service Fees"* (BFSFs) paid to PBMs/specialty pharmacies in Medicare Part D and other federal drug programs. In the *"Cost Approach"*, Service Vendors are entitled to a *"reasonable profit"*, after covering the documented cost of providing an itemized service (e.g. staff wages, staff time, materials). As such, with the usage of each of these similar MS therapies in varying degrees of significant decline in recent years, the Manufacturer Defendants fee payments to PBM Defendants for legitimate *"bona fide"* services associated with these drugs should also be stagnating or eroding, barring a significant change in the nature or number of services provided. The Relator's investigation has not identified any factors to justify increased BFSFs in the face of declining usage. For instance, there is no evidence of a significant number of new services being provided by the PBM Defendants for the Manufacturer Defendants' MS drugs. In addition, there is no evidence of a significant increase in either wages or time required for specific services provided for the Defendants' MS drugs. According to the Bureau of Labor Statistics, wage inflation has only averaged 1-3% per year since the 2006 start of Medicare Part D. The Relator found no public data indicating that wage inflation for the Manufacturer or PBM Defendants differs significantly from these broader trends. However, despite these clear expert valuation recommendations, the Relator has determined that the Manufacturer Defendants are instead providing the PBM Defendants excessive payments in Medicare Part D far in excess of

FMV by employing service contracts based upon a "M*arket Approach/Percent of Revenue*" model, including the benefit of recent massive price increases.

128. In a September 2012 presentation to pharmaceutical industry manufacturer clients, the leading FMV consulting firm, Huron Life Sciences, provided an *"Example Service Fee Analysis"* for a typical *"product adherence program"* provided by PBMs/specialty pharmacies for manufacturers. See **Exhibit 24**. In the example, the Huron analysis indicates that the FMV analysis of a *"call"* to a patient using the *"Cost Build-up Approach"* should be a very straightforward calculation of the manpower and time needed to provide the service. For a *"medium complexity"* interaction, less costly personnel may be necessary, with the FMV of the call calculated by multiplying the *"labor price per hour"* of a *"staff nurse"* by the time duration of the interaction. For a *"high complexity"* call, greater expertise may be required, with the FMV determined by multiplying the higher hourly rate of a *"pharmacist"* by the time required. For an entire program or contract, the FMV would simply be a reasonable cost-based estimate of a sum of these individual service episodes. However, because standard Manufacturer Defendant service contracts are based upon a *"Market Approach/Percent of Revenue"* methodology without adjustments for extreme price increases, the PBM Defendants are instead receiving fraudulently high service fees tied to collusive pricing activity within the Medicare Part D program.

129. Primarily driven by extreme price increases, spending on specialty drugs, including the Manufacturer Defendants drugs in the large MS therapeutic category (the largest spending category in the majority of Part D plans), have been the key driver of US pharmaceutical spending growth over the past 5-7 years. According to most healthcare experts, including the PBM industry itself, specialty drugs are expected to account for virtually all US drug spending growth going forward. In addition, after years of growth and consolidation, the PBM industry is now very mature with more than an 80% penetration of US insured lives. Furthermore, enrollment growth opportunities are relatively modest for the overall PBM industry outside of government programs, due to stagnant trends in the employer-based insurance market. In fact, the number of Americans with private health insurance (either employer-based or purchased directly) has declined from 203.2 million people in 2005 to 198.8 million people in 2012. *US Census Bureau*. On the other hand, enrollment in government insurance programs, namely Medicaid, Medicare Advantage and Medicare Part D, has grown robustly in recent years. According to the US Census Bureau, US Medicaid and Medicare enrollment grew from 38.2 million and 40.2 million people, respectively, in 2005 to 50.9 million and 48.9 million people, respectively, in 2012. In recent years, the growth of Medicare Part D PDP and Medicare Advantage plans has been even stronger. Medicare Advantage enrollment has grown from 5.6 million in 2005 to 13.1 million in 2012, accounting for the vast majority of the medical insurance growth in the Medicare program. As a reminder, in 2013, 83% of Medicare Advantage plans included a Part D drug benefit. *Medicare Advantage 2012 Data Spotlight, Kaiser Family Foundation*. See **Exhibit 25**. Including both stand-alone PDP

plans and Medicare Advantage-PD offerings, total Medicare Part D enrollment grew from 27.6 million beneficiaries in 2006 to 37.4 million beneficiaries in 2012. *2013 Medicare Trustees Report.* With passage of the ACA, government insurance programs will remain the key growth driver for PBM and managed care organizations (MCOs) in the years ahead.

130. With these industry dynamics, in a normally-functioning US marketplace, the PBM Defendants should be competing aggressively on several fronts in the pursuit of Part D and Medicare Advantage enrollment, especially regarding high-cost specialty drugs. First, in specialty drug categories crowded with numerous *"interchangeable"* therapies, such as is the case with the Manufacturer Defendants MS agents, the PBM Defendants should be aggressively seeking rebates/discounts for formulary access in pursuit of government program market share. With control of more than 80% of Part D enrollment nationwide, the PBM Defendants should have extraordinary leverage to employ branded *"therapeutic substitution"* programs, thus generating considerable discounts and savings for CMS and Part D beneficiaries. The massive price inflation of the Manufacturer Defendants MS drugs, despite declining usage and severe market share erosion, clearly indicatives that the PBM Defendants are not using their dominant negotiating leverage to garner savings for their clients. As will be discussed in detail later in the complaint, in the early 1990's, the PBM industry had a severe impact on the pharmaceutical industry with effective branded *"therapeutic substitution"* programs at a time when its market penetration (5-10%) of the US drug market was a fraction of its current oligopolistic dynamics. Clearly, recent anticompetitive activity has prevented effective "*therapeutic substitution"* programs and enabled severe price inflation in the US MS drug category.

131. Second, the PBM Defendants should also be competing aggressively for clients based upon *"services"* provided for specialty drugs. Indicative of collusive behavior, the competition to provide specialty drug *"services"* among the PBM Defendants in the US has been minimal in recent years. According to a January 2013 survey performed by Leerink Swann, a leading healthcare investment firm, less than 5% of the health plans identified specialty drug *"service"* capabilities as a key driver in its selection of a PBM to manage its drug benefit. On January, 13, 2013, a major investment firm held a conference call with David Dross, the National Leader of the Managed Pharmacy Practice for Mercer, a leading health consultant firm that advises major corporations and health plans. Regarding PBMs, the Goldman Sachs analyst concluded from the discussion: *"there is little differentiation among specialty (service) offerings, as lack of therapeutic alternatives result in few formulary choices". Goldman Sachs research note, 9/25/13.* This broad statement greatly oversimplifies the varying competitive dynamics in different specialty drug therapeutic categories. The potential for specialty drug price competition is understandably limited in disease categories with few similar treatment options. A clear example of a high-priced specialty drug facing little direct competition is Alexion's Soliris. As the only approved treatment for Paroxysmal Nocturnal Hematuria (PNH, a rare blood disorder), Soliris is similarly-priced in the $500,000 cost per patient per year range in the US and most developed

countries. In sharp contrast, competition, via both manufacturer discounts and specialty services, should be severe in the crowed MS market. However, rather than competing to save clients' money, the Relator alleges that the oligopolistic PBM/specialty pharmacy industry, dominated by the PBM Defendants, has benefited from a significant escalation in unjustified *"fees"* for largely *"commoditized"* and declining specialty drug services for the Manufacturer Defendants MS drugs via a collusive pricing scheme.

132. Most specialty drug manufacturers, including the Manufacturer Defendants, also directly provide extensive patient support services via websites and other avenues, including financial/insurance assistance, nurse and pharmacy services, injection training and education programs. In fact, a review of the MS drug websites of the Manufacturer Defendants (avonex.com, copaxone.com, rebif.com and betaseron.com) indicates support services that are quite similar to those provided by the PBM Defendants. As such, many potential services provided by the PBM Defendants for Medicare Part D beneficiaries may be redundant and therefore of no discernible value (i.e., a FMV of zero) to the Manufacturer Defendants. According to CMS statutes, payments for unnecessary or redundant PBM services, do not qualify for *"bona fide*" status under the Medicare Part D statutes. However, given the lack of CMS BFSF reporting requirements for manufacturers and PBM entities in Medicare Part D, without a thorough investigation, no parties other than the contracted entities themselves know either the actual services provided by PBMs for a particular manufacturer product or their itemized, assigned monetary values. As such, the Relator expects discovery will require particular diligence in reviewing both the FMV of *"appropriate"* services and identification of potential *"sham"* services/payments between the Manufacturer Defendants and the PBM Defendants.

133. According to CMS, all BFSFs must pass the so-called *"Four-Part Test"* in order to *"qualify"* for exclusion from Medicare Part D price calculations. The first three parts of the test are: a) the *"itemized"* service is actually performed; b) the manufacturer would otherwise perform or contract for the service in the absence of the service contract, and; c) the fee in not passed on in whole or in part to a client (in part D, almost always the plan sponsor) or customer of the entity. Important to this complaint, CMS has stated that *"the manufacturers may presume, in the absence of any evidence to the contrary, that the fee paid is not passed on"* (i.e., it is kept by the PBM, specialty pharmacy or other service providers). *71 Fed. Reg. 69624, 69667-9.*

134. However, the Relator views the final criterion of the BFSF *"Four-Part Test"* as the basis for the current fraud allegations. According to the Part D legislation, CMS places the full legal onus on the drug manufacturers (and not the PBM and other Service Vendors) to justify that the fees represent *"Fair Market Value" (FMV)* for the services rendered. CMS states: *"manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." 77 Fed. Reg. at 5332.* Furthermore, CMS has purposely kept its guidance

regarding FMV vague due to concerns about potential fraud, reiterating in its February 2012 proposed rule: *"We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define 'fair market value' at this time."* The same ruling further states: *"Due to the rapidly changing market in which new types of arrangements arise, we believe that manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." 77 Fed. Reg.*

135. The CMS *"Four-Part Test"* requirement to *"itemize"* BFSFs is also an important factor of consideration in these fraud allegations. Although CMS has not placed direct BFSF reporting requirements on drug manufacturers in Medicare Part D, said manufacturers must provide considerable BFSF detail if requested by Federal authorities. The Manufacturer Defendants must produce documentation of individual services actually provided by PBM Defendants for specific products and the FMV assessment methodology used to assign appropriate value. Furthermore, starting in 2012 the CMS DIR *("Direct and Indirect Remuneration")* reports require plan sponsor to maintain documentation of BFSFs. In the Relator's view, meeting these CMS requirements could prove challenging, particularly for the Manufacturer Defendants. First hand feedback from industry insiders, as discussed later in the complaint, indicates that documentation of BFSFs has been lax and cooperation between manufacturers and service vendors is often lacking.

136. In 2006, CMS also enacted regulations further clarifying BFSFs. The regulations expressly re-affirmed that service payments must be for legitimate services rendered and thus not related to the price of the drug. *See Fed. Reg. 69624, 69668 (Dec 1, 2006) (relevant sections codified at 42. C.F.R. 414.802, 414.804).* Since massive price increases have been virtually the only factor driving revenue growth for the Manufacturer Defendants' MS drugs in Medicare Part D, the escalating service fees paid to the PBM Defendants in the program related to these drugs are, by definition, primarily tied to price increases (not increased service needs) and therefore illegitimate.

137. In its 2007 final rule, CMS also added that BFSFs should be *"associated with the efficient delivery of drugs",* a clarification that appears to underscore the fraud by both the Manufacturer and PBM Defendants. In the rule, CMS interprets the *"Four-Part Test"* to *"encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69667-6.* The Relator alleges that greatly escalating fees paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D, driven entirely by massive price increases in the face of eroding patient volume, fails this CMS *"efficiency"* requirement by a wide margin.

138. Further increasing the legal responsibility for proper FMV assessment by manufacturers, CMS states that BFSF payments in excess of FMV must be reported to CMS as price concessions to be used to lower drug costs in the program. As quoted from the Medicare Part D 2010 reporting requirements: *"when a Part D sponsor (directly or indirectly through a PBM) receives payments from pharmaceutical manufacturers for administrative services which are above the fair market value of the services provided, the difference between the price paid by the pharmaceutical manufacturer and the fair market value of the administrative service is considered DIR (Direct and Indirect Remuneration)."* Furthermore, prior case history *(American Lithotripsy Society v. Thompson, 215 F Supp. 2d 23 (200), US District Court, District of Columbia)* has established that payments in excess of FMV are in effect deemed "*payments for referral*", a violation of the Anti-Kickback Statute.

139. The Anti-Kickback Statute also requires that transactions be *"commercially reasonable". 69 Fed. reg. 16,093 (March 26, 2004)* According to the Statute's theory, most business transactions must be commercially reasonable or there would be no reason for them to occur. Furthermore, the Anti-Kickback Statute considers commercial reasonableness to be a separate and distinct process from whether a transaction is established at FMV. The Anti-Kickback Statute states: *"If compensation is based upon comparables, assurance is required that the markets are not "distorted" and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". OIG Supplemental Compliance Program for Hospitals, p 4866-67.* The Relator alleges that the Manufacturer Defendants are using *"comparable", "Market Approach/Percent of Revenue*" service contracts in Medicare Part D with the PBM Defendants and their specialty pharmacy subsidiaries. The Relator further alleges that this comparable *"Market Approach"* utilized by both Defendant parties in the transaction is fraudulent under the Anti-Kickback Statute because of collusive, anticompetitive pricing activity in the US MS marketplace.

140. The Anti-Kickback Statute also separately requires that, in any compensation arrangement, the payment must represent *"reasonable compensation". 26 C.F.R. 1.162-7 (b) (3) (2004).* The Relator alleges that the excessive fees paid by the Manufacturer Defendants, based upon collusive market pricing, fails this Anti-Kickback requirement by a wide margin. In the Relator's estimation, the Manufacturer Defendants have provided the PBM Defendants with greatly escalating fee payments in Medicare Part D since the start of the program, despite stagnating or declining service needs for their respective products.

141. In order to demonstrate the magnitude of the BFSF fraud in this case, the Relator made calculations based upon *"percent of revenue"* payment assumptions in service contracts between the Manufacturer and PBM Defendants. In these calculations, the Relator has employed a stable *"4% of revenue"* service contract rate, inclusive of the massive Manufacturer Defendants price increases. The *"confidential"* terms of service fee contracts between Manufacturer and PBM Defendants will be determined in discovery and

may vary considerably by both party, contract and year. As an external industry expert, not an insider, specific service contracts are not available to the Relator. Using the *"4% of Revenue"* service contract rate inclusive of massive price increases, the Relator estimates alleged BFSF fraud paid by the Manufacturer Defendants to Service Vendors of nearly $900 million from the 2006 start of Medicare Part D through 2013. Based upon market share data from Express Scripts, the Relator estimates that 12% of these fees were tied to Medicare Part D in 2006, with the Medicare share rising to 25% in 2013. See **Exhibit 2**. The true magnitude of the alleged fee fraud will be determined by a review of confidential service contract terms, as well as other financial transactions, between the Defendant parties during discovery.

142. The magnitude of fee fraud may be greater than these conservative estimates because the Relator's investigation, including first hand expert feedback, indicates that service contract fee rates for the oligopolistic PBM industry have been on the rise. Due to escalating industry PBM/specialty concentration and negotiating leverage, the larger PBM Defendants may be demanding higher service contract rates. Of course, the dollar amount of fraudulent BFSFs paid by the Manufacturer Defendants is dwarfed by the estimated $4.5 billion in excess Manufacturer Defendants Part D MS drug costs enabled by the price collusion between 2006 and 2013. In turn, the Medicare Part D service fee fraud and price collusion has also apparently been the key factor behind the estimated $20.0 billion in Defendant MS price collusive-based drug sales in the US commercial insurance marketplace between 2006 and 2013.

143. The extent of the Medicare Part D fee fraud is even more apparent when looking at the Relator's estimates of service fees per patient, given the declining usage of the Manufacturer Defendants' MS drugs. Modeling the same *"4% of Revenues"* terms inclusive of massive price increases, the Relator estimates that the annual fee paid per drug-treated patient by the Manufacturer Defendants to the PBM Defendants in the Medicare Part D program has increased by about 250% (nearly a five-fold increase) in 2013 compared to 2005 just before the start of Medicare Part D, despite an approximate 35-40% decline in US patient usage for the combined agents over the same timeframe. See **Exhibit 2**.

144. The extreme anti-competitive nature of the fraud uncovered in the Relator's investigation is clearly illustrated by taking a closer look at trends for Manufacturer Defendant Biogen's MS therapy, Avonex. Despite a more than 35-40% decrease in US patients treated with the drug during the time period, Defendant Biogen reported a 40% increase in US sales from $939 million in 2005 to $1.9 billion in 2013, driven entirely by massive price inflation. Modeling a modest *"4% of Revenue"* service contract inclusive of massive price increases, it is estimated that service fees paid to PBMs/specialty pharmacies for Avonex increased from about $33 million in 2005 to $70 million in 2013, an 111% increase over the period. With the significant decline in patients on the drug, using the same service contract terms, it is estimated that Defendant Biogen paid approximately $496 in service fees per Avonex patient in 2005, which rose to $2,202 per patient in 2013, more

than quadrupling over the period. See **Exhibit 2**. As with be discussed later in greater detail, the signs of fraud are even greater for Biogen and the other Manufacturer Defendants in 2013 when accelerating volume erosion due to severe new MS drug competition has been accompanied by a further acceleration in already severe price inflation. This massive disconnect between calculated fee income and patient volume strongly supports the Relator's allegations of extreme BFSF FMV fraud by Defendant Biogen. Similar fee dynamics are found for the other Manufacturer Defendants MS drugs.

145. The anticompetitive nature of pricing for the Manufacturer Defendants' MS therapies and other specialty drugs is clearly indicated by an analysis of CMS's own Part D drug cost data. In order to assess availability and price competition for major specialty drugs among Medicare Part D plans, in September 2013 the Relator performed an analysis using the eHealth www.planprescriber.com search engine, an aggregator of CMS-approved data. For three major zip codes in the New York City, Los Angeles and Minneapolis area, the availability and pricing of a wide array of leading specialty drugs were reviewed for all available Medicare Part D plans in each respective region. See **Exhibit 26**. First, despite being in categories with numerous therapeutic options (e.g., multiple sclerosis, rheumatoid arthritis, hepatitis C, diabetes) which should enable aggressive pharmacy management tactics (e.g., formulary restrictions), all screened specialty drugs were equally available in all 80 Part D plans across the three geographic locations. Second, while a narrow band of pricing was expected due to limited specialty drug competition, the search in fact found that prices for all the screened agents were virtually identical across all plans and regions, indicating a complete absence of specialty drug price competition. As of September 2013, after years of near lock-step severe inflation, the beneficiary *"negotiated"* cost for three of the five Manufacturer Defendants MS drugs (Avonex, Copaxone and Rebif) was virtually identical in the $42-50,000 per year range in every Part D plan serving the New York, Los Angeles and Minneapolis metropolitan areas. The extreme price inflation and complete lack of variation for the three Manufacturer Defendants MS drugs, as well as other leading specialty drugs, indicates near complete price collusion between manufacturers and the PBM/specialty pharmacy industry. The data presented in **Exhibit 26** regarding Rebif pertains to the lower 22 mcg dose, which pricing databases indicate costs less the higher 44mcg dose used in some MS patients. Of note, when the Relator sought to expand this pricing analysis in November 2013 to include Betaseron, higher dose Rebif, as well as to include other geographic areas, the *"total drug cost"* data was no longer available on the eHealth website. The Relator has not been able to locate a current public database that enables individual *"total drug cost"* comparisons across Medicare Part D plans, although this data is undoubtedly available directly from CMS on a plan by plan basis on its planfinder website. The Relator has retained printed copies of the September 2013 eHealth drug cost comparison for review by either the court or other federal representatives. Nonetheless, the Relator would expect discovery to uncover virtually identical pricing in 2013 for the Manufacturer Defendants MS therapies in the vast majority of Medicare Part D plans across the nation, indicative of significant collusive behavior.

146. In order to gain a better understanding of competitive dynamics, the Relator took a closer look at the Medicare Part D plans listed as available, as per the same website, in Los Angeles in September 2013. A Relator search of individual plan websites was then performed in order to verify Part D sponsors for each plan, as well as to determine the PBM responsible for administering the drug benefit for each plan. While the large number of listed plans in Los Angeles might suggest wide options for beneficiaries, a closer look at the market clearly indicates minimal true competition. Although 27 plans were listed as of late September 2013, these only represented 10 distinct plan sponsors in the Los Angeles area, with all the plan choices managed by only 6 PBMs. Furthermore, 44% of Los Angeles plans were managed by Express Scripts and 18% by CVS/Caremark, together accounting for nearly two-thirds of Part D offerings in the Los Angeles area. See **Exhibit 27**. With the dominance of Express Scripts and CVS Caremark, the uniform pricing of specialty drugs across all Part D plans in Los Angeles is not surprising. See **Exhibit 28**. Of note, the Relator found a nearly identical breakdown of PBM market share and similar uniform pricing when evaluating the plan options in the New York and Minneapolis areas. With collusive drug pricing likely set by manufacturers with the dominant PBMs/specialty pharmacies, smaller PBMs likely must accept the same price but with less favorable contract terms. Regardless, all PBMs/specialty pharmacies that contract with Part D sponsors are likely benefiting to varying to degrees through escalating service fees from massive specialty drug price inflation since the 2006 start of the program.

147. As pertaining to this case, the publicly-traded PBM Catamaran made a definitive disclosure in the history of the secretive PBM industry at its November 2012 Investor Day. For the first time in PBM history, Catamaran provided valuable insights into the shifting profitability drivers in the PBM industry. See **Exhibit 29**. Catamaran's SVP of Pharmacy Operations, Albert Thigpen stated that Catamaran's profits margins on traditional retail prescriptions had fallen in half between 2008 and 2012. In the mail order segment, Catamaran's prescription profit margins had increased very *"modestly"* over the same time frame. Based upon the scale in management's own chart, each mail prescriptions generated approximately 14 times the profits of a retail prescription in 2012, versus about 7 times the retail profitability in 2008. More importantly, Mr. Thigpen stated that the profitability of specialty drugs had vastly improved over the four years, more than *"tripling"* between 2008 and 2012. Again, based upon management's own chart from the presentation, each specialty drug prescription generated about 6 times the profit of a mail prescription in 2012, up from about a 3-4 times ratio in 2008. Furthermore, the profitability of individual retail prescriptions for Catamaran in 2012 was minimal compared to that of a specialty prescription.

148. Given its small market share, the impressive specialty drug profitability transition at Catamaran in recent years suggests that trends are likely even more favorable at larger PBMs with greater negotiating leverage. Of note, as far as the Relator is aware, no other PBM has ever publicly-discussed in detail the profitability dynamics of their retail, mail order and specialty pharmacy segments. As indicated in **Exhibit 30**,

Catamaran has only about a 4% market share of entire US PBM market in 2013, compared to 27% and 21% for Express Scripts and CVS Caremark, respectively. As indicated in **Exhibit 31**, despite recent aggressive growth, Catamaran has an even smaller share of US market for specialty drugs. For 2011, Catamaran accounted for less than 2% of US specialty drug sales (within the *"other"* category in **Exhibit 31**), compared to 30% and 23% for Express Scripts and CVS Caremark, respectively. Specifically within the Medicare Part D program, Catamaran's market share is similarly modest. According to the Relator's September 2013 analysis of all available Part D plans in the New York, Minneapolis and Los Angeles areas, Catamaran managed approximately 7% of plans, compared to 44% and 19% for Express Scripts and CVS Caremark, respectively. See **Exhibit 27**. With far greater market shares and negotiating leverage, the Relator has no doubt that discovery will indicate that the *"tripling"* of specialty drug profitability at Catamaran between 2008 and 2012 will be equaled or more than likely exceeded by the larger PBMs driving the US market.

149. Other than FMV BFSF-related price collusion between the Manufacturer Defendants and the PBM Defendants, the Relator's extensive investigation has not uncovered any other *"plausible"* rationale for the massive US inflation of the long-standing, *"interchangeable"* Manufacturer Defendants MS therapies since 2006. First, none of the Manufacturer Defendants has disclosed any clinical or corporate factors in recent years to enable or justify the severe US price increases. Second, through investigation and insider commentary discussed later in the complaint, the Relator has also documented the rising negotiating leverage of large Service Vendors, including the dominant PBM Defendants in Medicare Part D, relative to manufacturers in recent years. As such, it defies both common sense and competitive theory that the oligopolistic PBM industry would permit the massive, near lockstep, US price increases for the Manufacturer Defendants' MS therapies in Medicare Part D without receiving a considerable increase in compensation. With BFSFs documented as the primary source of PBM compensation in Medicare Part D (as will be discussed in detail in the next section), these payments to the PBM Defendants have undoubtedly significantly increased along with the massive price inflation for the Manufacturer Defendants MS drugs.

MEDICARE PART D: PBM COMPENSATION DRIVEN BY BFSFs, NOT REBATES

150. When the Medicare Part D program began, both legislators and CMS expected private competition to generate significant cost savings for seniors and to hold down drugs prices. In October 2003, as Congress was debating the Medicare Part D legislation, President George W. Bush claimed: *"The best way to provide seniors with modern medicine, including prescription drugs coverage...is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices."* In November 2003, Secretary of Health and Human Services, Tommy Thompson, stated: *"Health insurance companies are going to get into this market...The pharmaceutical benefit*

managers (PBMs) who will be taking over purchasing of the drugs are going to be able to purchase in bulk with the pharmaceutical companies and hold down prices." Key government officials actually suggested Medicare Part D drug cost savings would be even greater than in other federal drug programs, such as Medicaid. While awaiting implementation of the program, in September 2004, Medicare Administrator Mark McClellan claimed that the private insurers would be able to obtain *"the best"* prices for seniors. He stated: *"Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation."* The above comments were excised from an October 2007 report, entitled *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Cost of Medicare Drug Coverage* by the US House of Representatives, Committee on Oversight and Government Reform, which was chaired by Henry A. Waxman. Two things regarding these statements are noteworthy as pertains to this complaint. First, as stated in the Waxman report, claims regarding Medicare Part D *"private competition savings"* during the legislative process were all *"theoretical"* at the time, not based upon any detailed analysis in the public domain. Second, the Relator has found no evidence that the proponents of the Part D legislation voiced any concern regarding the lack of Medicare Part D legislative protection against severe drug price increases, which is provided in other federal drug programs.

151. Legislative proponents and CMS clearly expected significant *"negotiated"* rebates/price concessions from drug manufacturers to be the primary method to limit elderly drug costs, to prevent severe brand drug price inflation and to compensate PBMs and other Service Vendors for their efforts in the Medicare Part D program. On the other hand, the Relator has found no evidence of legislative debate regarding the role of *"Bona Fide Service Fees"* (BFSFs) in Medicare Part D, with the issue remaining largely out of the public eye even now more than seven years since the program's inception.

152. CMS's own data indicates that actual execution of the Medicare Part D program has been far different compared to initial expectations. Overall Part D spending was actually significantly below initial expectations in the first few its first few years of the program. As will be discussed in detail later in the complaint, these early program spending trends were due to an overly aggressive initial forecast and broad US drug industry factors unrelated to Part D's *"private competition"* design, including major patent expirations and a broad economic slowdown. A more detailed discussion of past and future Medicare Part D spending trends is provided later in the complaint. More central to this complaint, considerable branded drug inflation in Medicare Part D commenced as soon as the program was implemented in January 2006. According to CMS's own data reported in comments to a January 2010 General Accounting Office (GAO) report (*GAO-10-242*): *"An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier) between January 2006 and October 2009."* As discussed in this complaint, the price increases for many specialty drugs, including the Manufacturer Defendants MS therapies, have been far more severe compared to this broad index both before and after October 2009.

153. In addition, counter to the CMS expectations discussed above, the percentage rate of rebates in Medicare Part D have been very modest compared to other federal programs. As per the annual Medicare Trustee reports, Medicare Part D manufacturer rebates have remained in the 9-11% of overall program spending range for each year from 2006 through 2013, despite severe price inflation for many brand name products, including the Manufacturer Defendants MS drugs. See **Exhibit 22**. As such, with a stable rebate rate for price concessions, the profitability of many branded drugs for manufacturers (and PBMs/specialty pharmacies and other Service Vendors) has greatly escalated in Medicare Part D along with the considerable price inflation. The Medicare Trustees report forecasts a slight decrease in manufacturer rebate rates to an average of 10% of annual Part D spending out to the year 2022. If this CMS rebate rate forecast holds true, manufacturers (and Service Vendors) will to continue benefit significantly from program drug price increases. In sharp contrast, government rebates in the Medicaid program have been far larger, averaging 34% of program spending for the years 2006 through 2009. See **Exhibit 32**. The far larger Medicaid rebate rate is primarily because its statutes, in sharp contrast to Medicare Part D, require that manufacturers provide additional rebates to CMS for any revenues generated by price increases greater than CPI-U (Consumer Price Index-Urban).

154. Of note, the large cost savings divergence between Medicare Part D and Medicaid has significant spending and fraud implications for the former *"dual eligible"* population (i.e., Americans who were eligible for both Medicaid and Medicare prior to the start of Part D). In 2006, as part of the Part D legislation, 6.2 million *"dual eligibles"* had their drug benefit switched from Medicaid to Medicare Part D, based upon expectations of greater *"private competition"* savings that have clearly not materialized. Former *"dual eligibles"* now account for two-thirds of the Part D low-income subsidy (LIS) beneficiaries, who, in turn, account for the majority (70%) of specialty drug spending in the program. *(CBO Report, "Spending Patterns for Prescription Drugs under Medicare Part D, released December 2011)* With the federal government covering nearly 100% of drug costs for LIS beneficiaries, the vast majority of accelerating US specialty drug spending in Medicare Part D is funded by general taxpayers. The overall low out-of-pocket Medicare beneficiary exposure to high-priced specialty drugs (less than 6% in 2007 according to the General Accounting Office (*GAO 10-242, released January 20*10), as well as a significant increase in corporate Patient Assistance Programs (PAPs) have been key factors enabling drug manufacturers to avoid significant public scrutiny regarding severe price increases.

155. Due to the lack of price inflation protection in Medicare Part D and the unprecedented price increases since the start of the program, the Manufacturer Defendants' MS drugs (and many other specialty drugs) now cost magnitudes greater in Part D compared to Medicaid and the related 340B drug program. In May 2013, the Relator obtained *"confidential"* data (which can be confirmed with any 340B-participating drug wholesaler) regarding the pricing of Manufacturer Defendant Biogen's Avonex, Defendant Teva's Copaxone

and Defendant Bayer's Betaseron in the 340B program. The 340B program was created in 1992 to provide discounts on outpatient prescription drugs to Medicaid-ineligible patients via select safety net providers. By law, the *"discount for approved 340B providers is the same as that for state Medicaid providers". National Association of Community Health Centers, May 2011 "Understanding the 340B Program*". As indicated in **Exhibit 11**, in 340B and Medicaid, all three Defendant drugs are available at an 80-99% discount to the Average Wholesaler Price (AWP). This massive cost discrepancy has occurred because the Medicaid/340 B legislation has prevented manufacturers from benefiting from price increases beyond CPI-U since 1991-1992. As a historical reference, Biogen's Avonex was launched in the US at a cost of about $7,000 per patient per year in 1996, with the private market price rising to the $12,000 per patient per year range in 2005 before the start of Medicare Part D. Since 2006, the price increases for Avonex and other Manufacturer Defendants MS drugs have been far more extreme, with the cost per patient per year in Medicare Part D and the private insurance market rising to the $22,000 range in 2008 and to the $54-60,000 range by the end of 2013. As noted, this massive price inflation has occurred without any intervening justifiable factors, such as new medical uses or increased manufacturing costs. As such, the shift of *"dual eligibles"* from Medicaid to Medicare Part D has greatly escalated the drug cost of treating MS patients, with virtually all of the increase borne by Federal/State governments and general taxpayers. The Relator alleges that the vast majority of this increased drug cost burden has been caused by FMV BFSF fraud in the Medicare Part D program.

156. By law, all rebates/price concessions in Medicare Part D, whether retained by the PBM/specialty pharmacy or passed on to the plan sponsor, are applied by CMS to lower drug prices and beneficiary costs in the program. When Part D was enacted, legislators and CMS expected PBM compensation to be primarily via *"retaining"* a portion of rebates negotiated from manufacturers on behalf of plan sponsors. However, CMS's own data clearly indicates that execution of the program regarding PBM activities has been far different from expectations as well. In fact, the Relator's investigation has determined that the vast majority of PBM compensation in Medicare Part D since the program's inception has come not via traditional rebates/price concessions, but rather via BFSFs from manufacturers. In March 2011, the Office of Inspector General (OIG) of the Department of Health and Human Services released a report entitled *"Concerns with Rebates in the Medicare Part D Program"*, apparently the first and only public federal analysis/discussion of manufacturer rebate trends in the program. (*OIG HHS Report, OEI-02-08-00050, March 2011*) The OIG analysis was based on all Part D sponsor rebate reports and plan bid data for 2008, as well as an in depth review of six selected sponsors. Consistent with the above discussion, the OIG disclosed that Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008, corresponding to approximately 10% of total gross Part D drugs costs of $63 billion for the year.

157. However, central to these fraud allegations and contrary to legislative expectations, **PBMs *"RETAINED "* LESS THAN 1% OR ONLY $24 MILLION OF THE $6.5 BILLION** in total rebates

reported to CMS in plan sponsor *"Direct and Indirect Remuneration"* (DIR) reports for 2008. In addition, 61% of plan sponsors reported that PBMs retained no Part D rebates in 2008. Of note, while other types of price concessions (such as discounts from pharmacies for prompt pay and legal settlements) are included in the DIR reports, manufacturer rebates accounted for 98% of all price concessions received by plan sponsors in 2008, according to the OIG report. As such, counter to legislative expectations, PBMs received minimal rebate compensation from drug manufacturers in 2008. See **Exhibit 33**.

158. As stated in the Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: *"CMS considers all remunerations received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide service fees, to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor."* As such, since BFSFs are, by law, the only significant payments excluded from Part D sponsor DIR reports, virtually all PBM compensation in 2008 beyond the minimal reported retained rebates came in the form of BFSFs from manufacturers. However, as discussed at the start of the complaint, there is some possibility that PBM Defendants are hiding other fraudulent payments, not classified as BFSFs in Part D, within specialty pharmacy subsidiaries. Both manufacturers and PBMs are highly motivated to utilize BFSFs as compensation rather than traditional rebates, since the latter would serve to lower Part D drug prices and lead to lower future corporate revenues and profits. In contrast, BFSFs are excluded from government *"negotiated price"* calculations, leading to higher drug prices, as well as greater corporate revenues and profits.

159. Two other facts verify that the vast majority of PBM compensation in Medicare Part D has come via manufacturer BFSFs, rather than as expected from manufacturer rebates/discounts. First, as documented previously, the Medicare Trustee Reports confirm a similar 9-11% rebate rate for each year of Medicare Part D since inception. Despite considerable branded price inflation in Medicare Part D since the start of the program, elderly beneficiaries have not benefited from greater PBM negotiating leverage after 2008. As such, the majority of the incremental financial benefit from ongoing Part D drug price inflation since 2008 has accrued to manufacturers and likely their PBM/Service Vendor partners. Second, as discussed previously, the severe end-user inflation in Part D for the Manufacturer Defendants MS drugs has been well-documented in public pricing databases and CMS's own data. With this massive price inflation for the Defendants' MS drugs in Part D, it is certain that PBMs have *"retained"* similar low levels of manufacture rebates in more recent program years because any retentions would be reflected in lower current CMS and beneficiary drug prices, as required by the Medicare Part D statutes. As such, additional PBM Defendants compensation associated with the massive Manufacturer Defendants MS drug price inflation since 2008 came primarily via escalating, fraudulent BFSFs.

160. Additional direct CMS data confirms the extreme price inflation and low level of rebates for two of the four Manufacturer Defendants MS drugs, Biogen's Avonex and Teva's Copaxone. In January 2010, the General Accounting Office (GAO) released a report (*GAO-10-242*), entitled: *Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier"*. The report, commissioned by the Chairman (Pete Stark) of the Subcommittee on Ways and Means, Committee on Ways and Means of the House of Representatives, appears to represent the only specific, publicly-available, federal analysis of specialty drugs in Medicare Part D since the start of the program. The Relator has not been able to locate in the public domain any detailed assessments of specialty drugs in Medicare Part D by CMS itself.

161. In the analysis, the GAO obtained specialty drug pricing and price concession data for 20 key specialty drugs from 7 large plan sponsors, which represented 51% of all Medicare Advantage Part D enrollment and 67% of standalone Part D enrollment in 2008. In the report, the GAO identified ten chronic conditions commonly treated with specialty drugs; then selected two therapies for evaluation from each therapeutic category, unless only one appropriate drugs was available. In the multiple sclerosis category, the report disclosed the average *"negotiated price"*, as well as the *"average cost after price concessions"*, for Biogen's Avonex and Teva's Copaxone in these large Part D plans for the years 2006, 2007 and 2008. See **Exhibit 34**. For Biogen's Avonex, the annual Part D cost of therapy per patient *"after price concessions"* rose from $16,764 in 2006 to $18,528 (+12% year over year) and $22,608 (+23% year over year), a cumulative price increase of 35% over the two program years. For Teva's Copaxone, the annual Part D cost of therapy per patient *"after price concessions"* rose from $16,440 in 2006 to $18,264 (+13% y/y) to $20,784 (+13% year over year), a cumulative price increase of 26% over the two program years. The Part D price increases for these two MS agents were greater than for all other screened specialty drugs, except for Actelion's treatment for pulmonary hypertension, Tracleer, which had a similar cumulative price increase (27%) over the two years. Of note, public pricing databases indicate that the US cost of both Avonex and Copaxone was considerably lower still in 2005 (estimated in the $12,000 cost per patient range) just prior to the start of Medicare Part D. As such, the Relator estimates cumulative Part D price increases for Biogen's Avonex and Teva's Copaxone in the 60-75% range during the first three years of the program, consistent with the trends previously discussed. Public data indicates similar price increases for the other two long-marketed Manufacturer Defendants MS drugs, EMD Serono/Pfizer's Rebif and Bayer's Betaseron. As previously noted, CMS's own data indicates that Medicare Part D price inflation for the Manufacturer Defendants MS drugs has been even greater for plan years after 2008.

162. Central to the Relator's fraud allegations, the January 2010 GAO report also disclosed very modest levels of *"rebates/price concessions"* in Medicare Part D for the two selected MS drugs, as well as other specialty drugs. Regarding Biogen's Avonex, of the 7 large plan sponsors surveyed, only 3, 4 and 5 of

them reported obtaining ANY price concessions from the manufacturer for the years 2006, 2007 and 2008, respectively. Furthermore, despite Avonex's severe 35% price inflation between 2006 and 2008, the average level of rebates remained very low at 1.1%, 2.2% and 2.6% of the *"negotiated prices"* for 2006, 2007 and 2008, respectively. See **Exhibit 34**. The level of rebates for Teva's Copaxone were higher (6.2%, 8.0% and 7.2% of negotiated prices for the years 2006, 2007 and 2008, respectively) than for Avonex each year, but still below the program average of 9-11% reported by plan sponsors for each year of the entire program.

163. Given the low rebate rates for Avonex and Copaxone and the documented minimal level of PBM *"retained rebates"* in 2008 (as per the prior discussed OIG report), it can be concluded that PBMs received minimal rebate compensation from the manufacturers for both these products that year. Furthermore, given the stable program rebate rates and the extreme subsequent end-user price increases for these two drugs in Part D, it is certain that *"retained rebates"* have remained a very small portion of PBM compensation through 2013. As such, the vast majority of PBM Defendants compensation for Avonex and Copaxone has been via BFSFs in Medicare Part D since inception of the program, unless other types of fraudulent payments within specialty pharmacy subsidiaries are not being properly reported as discounts/price concessions.

164. All seven plan sponsors interviewed for the January 2010 GAO report indicated a *"limited ability"* to negotiate price concessions with manufacturers for specialty drugs. Key reasons they gave included a lack of competitors for many of these drugs, the low utilization of some drugs and CMS formulary requirements that limit the plan's ability to exclude drugs from formularies. Despite documentation of the dominant role of PBMs in Part D price negotiations, GAO appeared not to appreciate the influence of these organizations in the program. In fact, PBMs are only cursorily mentioned on page 12 of the document: *"Plan sponsors may use pharmacy benefit managers (PBM) to negotiate with manufacturers".* In addition, the report did not contain any discussion of factors behind varying pricing and rebate trends among specialty drug categories or individual drugs. As such, the GAO appeared not to recognize the considerable plan savings opportunities via the effective employment of proven PBM tactics (e.g., *"therapeutic substitution"*) in crowded, largely interchangeable, specialty drug categories, such as multiple sclerosis.

165. For its January 2010 specialty drug analysis, the GAO also sought comment from CMS, which proved to be quite limited in nature. As quoted from the CMS letter at the end of the GAO report*: "GAO reports that, on average, negotiated prices of the sample specialty tier drugs increased by 36 percent between CY 2006 and CY 2009. We would like to note that price increases are not unique to specialty tier drugs. An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand named drugs (both specialty and non-specialty tier drugs) between January 2006 and October 2009".* As such, CMS appeared not particularly concerned about significant specialty drug price increases because all branded drugs in the Part D program had inflated at a similar rate. CMS did not seem to appreciate that similar percentage

increases on high-priced specialty drugs had a far greater cost impact on Medicare Part D and its beneficiaries compared to lower-priced traditional drugs. To the Relator, the lack of CMS concern regarding severe price inflation and low rebate rates in the first three years of Medicare Part D by CMS is noteworthy because, when the legislation was passed, proponents expected severe private plan competition to yield price concessions greater than Medicaid. Furthermore, as with the GAO, CMS made no comments regarding pricing and rebate trends for specific therapeutic categories or individual drugs, with no concern expressed for the severe inflation regarding the Defendants Biogen's and Teva's long-marketed MS drugs. Finally, CMS made no mention of PBMs, indicating limited concern regarding the dominant role of these organizations in Medicare Part D. As such, similar to the GAO, CMS seemed unaware of the considerable potential for cost-savings in specialty drug categories, such as multiple sclerosis, which are crowded with numerous similar therapies.

DETAILS OF THE FALSE CLAIMS VIOLATION PATHWAY

166. For the Manufacturer Defendants:

1) The Manufacturer Defendants knowingly made fraudulent overpayments of *"Bona Fide Service Fees" ("BFSFs")* far in excess of the legally-required *"Fair Market Value" ("FMV")* to the PBM Defendants and their affiliates in the Medicare Part D program.

2) In reality, legitimate, typically patient/volume-driven service fee payments from the Manufacturer Defendants to the PBM Defendants for the formers' older MS drug in Medicare Part D should be in significant decline since the start of the program, commensurate with the eroding patient use of the drugs due to severe new drug competition.

3) As per the Complaint, the Relator has determined that the vast majority of PBM compensation for the Manufacturer Defendants' long-standing MS therapies in Medicare Part D since inception of the program has been via fraudulent FMV BFSFs, rather than manufacturer rebates/discounts/price concessions as anticipated by the legislation.

4) These fraudulent FMV BFSF payments were knowingly not disclosed to the Centers for Medicare and Medicaid Services *("CMS")* as price concessions/discounts by the Manufacturer Defendants as is their clear legal responsibility under CMS regulations, the False Claims Act and the Anti-Kickback Statute.

5) According to *31 U.S. code 3729*, anyone who *"knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"* faces liability. Despite not directly submitting claims for reimbursement, the Manufacturer Defendants have clearly *"caused"* government overpayments for their MS drugs via FMV BFSF fraud and related collusive drug price inflation.

6) As the dominant products in the large MS specialty drug category, the massive escalation in cost for the Manufacturer Defendant drugs (due to intentional BFSF fraud) has been a major data input for virtually all Part D plan sponsors across the nation in the bid process used to determine the level of Subsidy payments and premiums.

7) These fraudulent Manufacturer Defendant FMV BFSF payments knowingly resulted in massive fraudulent price inflation and overpayment by CMS in Medicare Part D for the Manufacturer Defendants' MS specialty drugs.

8) In the collusive scheme, the fraudulent FMV BFSFs paid by the Manufacturer Defendants knowingly *"caused"* the PBM Defendants to submit a wide array of false claims for payment to CMS for the fraudulently escalated MS drug prices, including annual DIR (*"Direct and Indirect Remuneration"*) Reports, PDE *("Prescription Drug Event")* data, annual beneficiary drug cost estimates in Part D plan bid submissions and drug cost data used in reconciliation.

167. For the PBM Defendants:

1) The fraudulent Manufacturer Defendants FMV BFSF overpayments to the PBM Defendants are kickbacks (i.e., *"payments for referral"*) and a violation of the Anti-Kickback Statute *(AKA)*. The fraudulent payments were made by the Manufacturer Defendants to the PBM Defendants in a quid pro quo exchange for favorable formulary positioning which enabled mutually-beneficial, massive and collusive, price increases reimbursed by CMS.

2) The willful receipt of these *"kickbacks"* is a criminal offense by the PBM Defendants since the CMS compliance regulations governing Part D require both Part D plan sponsors and Service Vendors *("First Tier, Downstream and Related Entities (FDRs)"* contracted by them to *"certify"* compliance with all relevant laws, including the AKA.

3) Case precedent has also clearly established violation of the AKA as a direct legal basis for filing a case pertaining to violation of both Federal and State False Claims Acts.

4) In the collusive scheme, the PBM Defendants also directly submitted false claims for payment in the PDE data filed with CMS with each fraudulently inflated MS drug prescription. While all of the 37 fields of the PDE report have been deemed *"claim for payment,("Spay vs. CVS Caremark")*, the specific PDE cost fields directly involved in this case include: Ingredient Cost Paid (#27), Patient Payment Amount (Field #32), Other TrOOP Amount (#33), Catastrophic Coverage Code (#26), Gross Drug Cost Below Out-of-Pocket Threshold (#30), Gross Drug cost Above Out-of-Pocket Threshold (#31), Low-Income Cost-Sharing Subsidy Amount (#34) , Patient Liability Reduction due to other Payor Amount (#35) and Covered Plan Paid Amount (#36).

5) The fraudulent PDE MS price/cost data has been knowingly used by the PBM Defendants (in their role as plan sponsors) to submit fraudulently high beneficiary cost estimates in annual Part D plan bids submitted to CMS.

6) The fraudulent Part D plan bids have resulted in the PBM Defendants knowingly receiving fraudulent payments from CMS associated with the collusive MS drug pricing, in the form of monthly *"Regular Subsidy"*, *"Low-Income Subsidy"* and *"Reinsurance Subsidy"* payments. As discussed in complaint, the majority of the fraudulent MS drug costs have likely occurred in the *"Low-Income Subsidy"* and *"Reinsurance Subsidy"* payments. As documented, the massive collusive pricing of the Manufacturer Defendants MS drugs has been the single largest driver of rising Part D costs in recent program years.

7) The fraudulent PDE MS drug price/cost data has also been utilized by CMS in the annual *"reconciliation"* process to fully reimburse the PBM Defendants (who bear no financial risk) for *"Low Income Subsidy"* and for 80% of non-LIS *"Catastrophic"* cost over-runs related to the collusive MS Part D drug price inflation.

8) Finally, given the severe and compounding nature of the collusive MS drug price inflation, the scale and magnitude of the fraud has greatly escalated each year since the 2006 start of Medicare Part D.

KEY ASPECTS OF MEDICARE PART D'S STRUCTURE CENTRAL TO THE FRAUD

168. CMS has established a unique bid and reimbursement process in the administration of Part D with plan sponsors. Under Medicare Part D, plan sponsors are required to submit bids to CMS in the first week of June for the following calendar plan year. The bids are based upon the sponsor's estimate of its anticipated monthly drug costs for Part D beneficiaries in the plan, as well as administrative costs and expected profit. *(OIG Report, Medicare Part D Reconciliation Payments for 2006 and 2007, OEI-02-08-00460, September 2009).* CMS uses the submitted data to determine individual plan premium rates and

monthly Subsidy payments made to plan sponsors for the following calendar plan year. The monthly Subsidy payment schedule of Part D is designed to help plans effectively manage *"cash flow"* during a plan year as actual drug costs accrue.

169. The plan sponsor bid cost estimates and related monthly Subsidy payments consist of four distinct tranches. First, the sponsor must provide a cost estimate for the *"basic"* Part D benefit for a beneficiary of *"average"* health in the plan, for which it receives monthly *"Regular Subsidy"* payments. According to CMS, the *"Regular Subsidy"* monthly payments for Part D plans across the US are relatively similar since the amounts are based upon national beneficiary cost averages, with modest adjustments for age and health status in each particular plan. Second, the plan sponsor must provide an estimate of the benefit cost for low-income (LIS) beneficiaries in the plan for the following calendar year, for which CMS provides monthly *"Low-Income (LIS) Subsidy"* payments. CMS covers the vast majority of drug costs for LIS beneficiaries in Medicare Part D. Third, the sponsor must estimate the cost of providing *"catastrophic"* drug coverage for non-LIS beneficiaries whose annual out-of-pocket spending exceeds the annual maximum threshold ($3,600 in 2006, rising to $4,750 in 2013). For *"catastrophic"* drug costs, CMS covers 80% of the estimated costs via monthly *"Reinsurance Subsidy"* payments; with plan sponsors and non-LIS beneficiaries responsible for 15% and 5% of spending over the threshold. In contrast to *"Regular Subsidy"* payments, monthly *"LIS Subsidy"* and *"Reinsurance Subsidy"* payments among plans can vary widely, depending upon the enrollment and health status characteristics of a particular plan.

170. Finally, starting in 2011, CMS added the *"Gap Discount Subsidy"* as part of the legislation requiring drug manufacturers to provide price discounts to all Part D beneficiaries in the so-called *"donut hole"* coverage window. Prior to 2011, non-LIS Part D beneficiaries were responsible for 100% of drug costs in the *"donut hole"* after exceeding their standard benefit spending limit and before reaching the *"catastrophic"* out-of-pocket threshold. For instance, in 2010, non-LIS beneficiaries were responsible for all drug spending between the standard benefit limit of $2,800 and prior to the $4,550 out-of-pocket limit, representing potential $1,700 of personal costs during the year. To decrease this financial burden, as part of the ACA, manufacturers participating in Medicare Part D agreed to provide a 50% discount for branded products within the *"donut hole"*. As will be discussed later in the complaint, while the manufacturer discounts have certainly helped many elderly beneficiaries, the legislation has likely further accelerated already severe price inflation for many specialty drugs, including the Manufacturer Defendants MS therapies. In plan bid submissions, plan sponsors must estimate the amount of manufacturer *"donut hole"* discounts for the following calendar year, for which CMS provides monthly *"Gap Discount Subsidy"* payments. CMS hired a Third Party Administrator (TPA), Palmetto GBA, to administer the Gap Discount program in Medicare Part D.

171. In **Exhibit 35**, the beneficiary cost-sharing requirements in Medicare Part D are provided for the 2012 plan year. As indicated, other than minor beneficiary co-payments, CMS covers all drug costs for *"Full"* Low-Income (LIS) Part D beneficiaries (i.e., enrollees with income less than 135% of the Federal Poverty Limit (FPL). For 2012, the Full LIS income cutoff was $15,080 and $20,426 for a single person and married couple, respectively. "*Partial"* LIS Part D beneficiaries (i.e., enrollees with income between 135% and 150% of the FPL), have modestly higher cost-sharing requirements, but this population is inconsequential to this case since they only account for 2-3% of Part D LIS enrollment. Due to their poor health, the smaller LIS segment (29-30% of overall Part D enrollment) accounts for the majority of expensive specialty drug use in the program. With the government covering all *"Full"* LIS drug costs, this population has virtually no awareness or sensitivity regarding to the massive price inflation for the Manufacturer Defendants MS drug and other specialty drugs in Part D.

172. The lack of price awareness and price sensitivity for LIS Part D beneficiaries was supported by the General Accounting Office (GAO) report released in January 2010, entitled *"Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier."* According to the GAO report, *"prescriptions for LIS beneficiaries accounted for about 70 percent, or about $4.0 billion of the $5.6 spent on specialty-tier eligible drugs under Medicare Advantage-PD and PDP plans that year (2007)….the fact that spending on specialty tier-eligible drugs in 2007 was largely accounted for by LIS beneficiaries is noteworthy because their cost sharing is largely paid by Medicare."* Due to CMS covering almost all LIS drugs costs, the GAO concluded: *"In contrast to the situation with non-LIS beneficiaries, differences in negotiated drug prices do not affect out-of-pocket costs for full subsidy LIS beneficiaries, and affect out-of-pocket costs for partial subsidy LIS beneficiaries only until they reach the catastrophic threshold."*

173. Each of the Part D Subsidy payment tranches completes a separate *"reconciliation"* process between CMS and plan sponsors approximately nine months after the close of each calendar plan year. As discussed previously, CMS covers all cost over-runs in a given plan year for LIS beneficiary drug spending; plans sponsors, as well as PBM contractors and drug manufacturers, bear no financial risk. Regarding the *"Gap Discount Subsidy"* payments, the Third Party Administrator apparently largely guarantees that the price discounts *"pass through"* from the manufacturers to CMS and plan beneficiaries; as such plan sponsors similarly bear no financial risk. However, for *"Regular Subsidy" and "Reconciliation Subsidy"* payments, both CMS and plan sponsors share some financial exposure for drug spending variations. However, as discussed previously, the plan sponsor risk only pertains to *"unexpected profits/losses"* above or below the *"expected profits"* in annual Part D bids. As discussed previously discussed, any modest potential financial risk pales in comparison to the gains from massive specialty drug price inflation throughout the Part D program. The PBM Defendants largest financial exposure pertains to escalating Catastrophic cost-

sharing requirements (15% plan sponsor responsibility) linked to severe specialty drug price increases. However, the Relator has determined that the Manufacturer Defendants are more than likely covering the majority of these sponsor cost-sharing costs via fraudulent, undisclosed BFSFs.

174. Regardless of ultimate financial risk, the extended timelines in the regulatory handling of Part D Subsidy payments suggest considerable challenges for Part D sponsors, especially regarding rapidly inflating high-priced specialty drugs as with the Manufacturer Defendants' MS therapies. As mentioned above, plan sponsors must submit cost estimates for all Subsidy payments six months before the start of the next calendar plan year. Furthermore, *"reconciliation"* of the *"Low Income"* and *"Reinsurance"* Subsidy payments for a given plan year does not occur until nine months after the end of said plan year, thus 27 months after the initial bid was submitted to CMS. Given the massive and relentless price increases since 2006 (often with multiple large price increases in a single year) for the high-budget Manufacturer Defendants MS drugs, in a non-collusive marketplace, the rapidly escalating beneficiary costs would wreak havoc on the *"cash flow"* of part D plan sponsors. The plan sponsor financial burden would be particularly severe due to their 15% cost-sharing responsibility for unlimited amounts of non-LIS Catastrophic drug costs. The PBM Defendants would be required to *"front"* the considerable *"unexpected"* drug costs associated with the massive MS drug price inflation, as well as for the considerable price inflation of many other specialty drugs in Part D. The sponsor would have to fund these added costs long before being reimbursed by CMS in full for LIS beneficiaries and for 80% for unexpected Catastrophic costs. Despite the PBM Defendants considerable financial risks associate with severe specialty drug price inflation, public commentary from the PBM Defendants regarding Part D subsidies and the *"reconciliation"* process has been scant.

175. However, the Relator views a corporate disclosure from PBM Defendant Wellcare in its 2013 10K filing with the SEC as particularly ominous and indicative of a high risk of collusive behavior between the Manufacturer and PBM Defendants. In the 10K, Wellcare states: *"Historically, we have not experienced material adjustments related to CMS annual reconciliation of prior year low-income cost sharing, catastrophic reinsurance subsidies and coverage gap subsidies."* As mentioned near the beginning of this complaint, this seemingly innocuous statement suggests significant collusion between Wellcare and specialty drug manufacturers, especially the Manufacturer Defendants of MS therapies in this case. Since Wellcare has not experienced any *"material adjustments"* pertaining to its *"Low Income"* and *"Re-insurance"* Subsidies for all years in which it has participated in Part D (2006 through 2011 have been *"reconciled"* with CMS at this point), the company is admitting it has been able to accurately *"plan"* for the massive price increases for the Manufacturer Defendants MS drugs (and other rapidly inflating specialty drugs) fully 6 months ahead of each plan year, in addition to *"planning"* for additional price increases during the subsequent Part D calendar year.

176. Such forecasting success, by Wellcare, for a single Part D year suggests acumen; accuracy for every Part D plan year would seem virtually impossible without collusion with the specialty drug manufacturers. The likelihood for collusion is heightened further because, as discussed in detail in this complaint, there is no rationale competitive market basis for the severe price increases since 2006 in Part D for the declining Manufacturer Defendants drugs in the increasingly competitive US MS category. Furthermore, if a small Part D plan sponsor like Wellcare (only 4.4% and 1.1% of PDP and MA-PD enrollment in 2012) has such remarkable "*visibility"* on pricing in the top-spending MS drug category in Part D, one can be assured that the remainder of the larger PBM Defendants have equal or better intelligence. In the Relator's view, Wellcare's commentary strongly indicates widespread collusive behavior by the Manufacturer and PBM Defendants in Part D that demands to be investigated aggressively.

SPECIFICS OF FRAUDULENT DATA SUBMITTED TO CMS

177. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile Subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan sponsors are required to submit PDE *("Prescription Drug Event")* records for each prescription of all covered drugs dispensed to enrollees. The PDE includes 37 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE does not provide drug costs paid by PBMs to drug manufacturers. In addition, sponsors must submit quarterly and year-end DIR *("Direct and Indirect Remuneration")* reports to CMS to disclose any rebates or price concessions, which almost entirely come from manufacturers via PBM negotiations for the vast majority of plans. Of note, both the PDE and DIR data are *"self-reported"*, with apparently limited CMS oversight or verification. *(Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010).*

178. For the vast majority of Part D plans, the PDE and DIR reports are prepared by contracted PBMs, with limited controls by either CMS or unaffiliated plan sponsors. As noted previously, for the Dominant PBM Defendants who control the majority of Part D enrollment, the plan sponsor, PBM and specialty pharmacy functions are all provided under the same ownership structure or by closely affiliated parties. The Relator has concluded that the dominance of these vertically integrated entities has greatly increased both concentration in the Part D program and the potential for fraudulent behavior. The CMS regulations clearly state that PDE and DIR data is used by CMS to complete the Part D plan reconciliation process, including for the *"LIS Subsidy"* and *"Reinsurance Subsidy"* payments which have been a major conduit for the alleged fraudulent MS drug reimbursement in this case.

179. By paying BFSFs far in excess of FMV to the PBM Defendants that serve to fraudulently escalate US MS drug prices, the Manufacturer Defendants are knowingly causing the collusive PBM Defendants to submit fraudulent *"claims for payment"*, in the form of Prescription Drug Event (PDE) data for each relevant prescription, to CMS. The Part D regulations clearly indicate that plan sponsors and PBMs are liable under the False Claims Act for fraudulent PDE data submissions to CMS due to their requirement to *"certify"* compliance with regulations as a prerequisite for participation and payment. The provision of C.F.R. § 423.505, entitled *"Certification of data that determines payment"* states:

> *(1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to the payment. The data may include enrollment information, claims data, bid submission data, and other data that CMS specifies.*
>
> *(3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fall back entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.*

180. The legal liability of the PBM Defendants in this current filing was definitively confirmed in recent case documents, including the Court Order and a Statement of Interest from United States Attorney in Pennsylvania, pertaining to another active Qui Tam case, the *United States of America, ex. rel. Anthony R. Spay v. CVS Caremark Corporation* (Civil Action No. 09-4672). In the Spay case, the Relator's company, Pharm/DUR, was hired in February 2007 by Medical Card System, Inc. (MCS, the second largest health administration and health insurance company in Puerto Rico) to perform a comprehensive audit of the Medicare Part D pharmacy claims paid by MCS for its Part D participants from January 1 through December 31, 2006. In June 2003, the Defendant in the case, CVS Caremark, entered into a PBM agreement with MCS, in which Caremark provided PBM services to the health insurance plans offered by MCS. As discussed in the Court Order (dated December 20th, 2012), based on the audit results, Spay alleged in his Amended Complaint that CVS Caremark *"regularly and knowingly submitted false and fraudulent PDE data items to CMS". Spay* alleged fraudulent PDE submission of inflated drug cost data and prescriber identification information, among other items, leading to false claims of more than $4 million.

181. In June 2011, the government notified the Court that it declined to intervene in the Spay matter. However, in September 2012, the government took the somewhat unusual step of filing a second Statement of Interest (pursuant to 28 U.S.C. § 517) *"to respond to certain arguments made by the defendants, Caremark, in their motion to dismiss the relator's complaint."* First, the US Attorney refuted the merit of Caremark's invitation to the Court to view the government decision not to intervene as an indication that Spay case lacked merit. The Government stated that Caremark's view *"is a totally unwarranted and inappropriate presumption." The Government's decision whether or not to intervene is based on many factors, including questions of resource allocation and judgments as to which types of cases it chooses to pursue at a given time."* In addition, the Government provided its legal opinion prior to the Court case review regarding several key Part D topics germane to both the Spay case and this current Qui Tam filing.

182. First, the Government verified the *"certification"* requirements for both Part D plan sponsors and participating subcontractors, including PBMs and specialty pharmacies. The Government stated:

> *"As a condition for receiving its monthly payment from CMS, a Part D plan sponsor must certify the accuracy, completeness and truthfulness of all data related to payment. Data related to payment may include enrollment information, claims data, bid submission data and any other data specified by CMS. 42 C.F.R. § 423.505(k)(l). If the claims data has been generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, that entity, contractor or subcontractor must "similarly certify" that the claims data it has generated is accurate, complete and truthful and must acknowledge that the claims data will be used for the purposes of obtaining federal reimbursement. 42 C.F.R. § 423.505(k)(3). The term "claims data referred to in 42 C.F.R. § 452.505 (k)(3) includes PDE records."*

The Government further stated:

> *"Part D plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(l). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions." 42 C.F.R. § 42 3.505(i)(4)(iv).*

183. Second, the US Attorney gave a definitive opinion in the Spay document that PDEs are *"claims"* under the False Claims Act, in a sharp rebuke to Caremark's attempt to position PDE data as unrelated to payment. The Government stated*: "On page 20 and 21 of their brief, defendants (i.e., Caremark) argue that "PDE data is not a claim under the FCA." Defendants are wrong." ... In its Part D regulations, CMS expressly refers to PDE submissions as "claims data". See e.g. 42 C.F.R. § 423.505 (k).*

Providing further granularity, the government stated:

> *"The purpose and function of PDE data put that data squarely within the FCA definition of "claim." As quoted above, CMS uses PDE data for "payment" and "validation" of claims. PDE data is also used by CMS as part of the year-end reconciliation process, which may result in additional money paid by the Government…In sum, because PDE records are an integral part of the process for determining Medicare payments to Part D plan sponsors, each PDE that is submitted to CMS is effectively a request for payment submitted to Medicare for each prescription filled under the Part D program."*
>
> *"On a final note, the United States submits that acceptance of the defendants' unduly narrow interpretation of "claim" could seriously undermine efforts by the United States to protect the integrity of the Part D program. If validated by the Court, the defendants' position may limit the Government's ability to use the FCA in the future to recover money improperly paid under Medicare Part D."*

184. In the Statement of Interest, the Government also refuted Caremark's attempt to categorize PDE as a *"public disclosure"*, which would negate the use of the data in FCA cases. *"Accordingly, the United States does not believe that the circumstances in which PDE data may, under very restricted circumstances, be released to entities outside the government for research purposes, suggests that the submission of PDE information for purposes of Part D payment qualifies as a public disclosure under the False Claims Act."* Of note, from 2006 to 2008, PDE data was not available to anyone outside of the government; beginning in 2008 it was available on a restricted basis only for *"research, analysis, reporting and public health functions." 73 Fed. Reg. at 30664.*

185. On December 20th, 2012, (three months after the above Government Statement of Interest), the United States District Court For the Eastern District of Pennsylvania issued its Court Order denying Caremark's Motion to Dismiss the Spay Qui Tam Case. In the decision, the Court fully supported the Government's Statement of Interest determinations regarding plan sponsor and PBM liabilities under the FCA as related to *"Part D certification"*, as well as PDE data status as *"claims for payment"*. In addition, the Court provided additional legal insights that are very pertinent to this current Qui Tam filing.

186. The Court determined that a primary basis for FCA violation in Part D is *"false certification"* of the *"truthfulness, accuracy and completeness"* of the data submitted by either plan sponsors or subcontractors (such as a PBM) as a *"condition of payment"*. Under the *"express false certification theory"*, an *"entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds."* The Court included PBMs and other contractors as legally liable, stating: *"When the claims data is generated by a subcontractor of a Part D Sponsor, such as a PBM, the subcontractor must similarly certify, as a condition of payment, the truthfulness, accuracy and completeness of data"…"In turn, failure of either a Part D sponsor or the sponsor's subcontractor to submit accurate, complete and truthful data related to payment*

may give rise to a FCA claim"…"The Amended Complaint (in Spay) goes on to allege that, in violation of Section 423.505(k), Defendants then falsely certified the truth, accuracy, completeness of those data (i.e., PDE) fields. Such allegations give rise to a proper claim under the False Claims Act."

187. A related statement from the Court regarding *"certification"* liability seems particularly important to this current Qui Tam filing. The Court stated: *"CMS's Prescription Drug Benefit Manual specifically envisions False Claims Act liability for the certification and submission of inaccurate or false PDE data. In the absence of such liability, a subcontractor to a Part D sponsor – in this case, Defendants (Caremark) – would be virtually unfettered in its ability to receive funds from the government while flouting the law."* As noted in this complaint, the PBM Defendants typically keep their plan sponsor, PBM and specialty pharmacy subsidiaries as separate legal entities. The Relator expects discovery will uncover that the fraudulent BFSFs and the related service contracts for many of the PBM Defendants may be domiciled in legal entities outside of CMS reporting requirements that are largely specific to plan sponsors (for both rebates/price concessions for all program years and for BFSFs starting in 2010). Holding both plan sponsor and related subcontractor entities in Part D legally accountable may be important for prosecuting the PBM Defendants for the alleged fraud outlined in this case.

188. In *Spay*, CVS Caremark also alleged that while the Defendant supplied PDE information to CMS, it did not request or demand payment, and, therefore submitted PDE data is not a claim for payment on which FCA liability can be based. The Defendant argued: *"Rather, the PDE records, which the Plaintiff alleges are "claims" or "requests for payment" under the FCA, are nothing more than data used for accounting purposes and for MCS's and CMS's year-end reconciliation process."* The Court disagreed outright in reciting CMS instructions: *"every time a beneficiary fills a prescription covered under Part D , plans must submit…PDE record to CMS" (CMS Instructions 6). "The PDE record contains prescription drug cost and payment data <u>that will enable CMS to make payment</u> to plans and otherwise administer the PDE benefit." (Id.) "They go on to note that the submitted data components fit together to allow calculation of payment under the four legislated payment mechanisms." These PDE records are "conditions of payment" that are necessary for CMS to carry out payment provisions…of the Act." (id. at 9.)*

189. The Court went on to directly link these PDE responsibilities to the FCA. *"According to the CMS Prescription Drug Manual, Chapter 9 § 80.1, CMS states: When submitting claims data to CMS for payment, Sponsors and their subcontractors <u>must certify that the claims data is true and accurate</u> to the best of their knowledge and belief. The False Claims Act is enforced against <u>any individual/entity</u> that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government."* Finally, the Court made a noteworthy definitive statement regarding the central role of PDE data for payment in Part D: *"Indeed, the PDE data is the <u>only</u> record submitted from PBMs and Part D*

sponsors that triggers CMS's payment obligation to the Part D sponsor."

190. Related to this issue, CVS Caremark also argued in Spay that their PDE data submissions could not be false records because the Defendant was paid by MCS, not directly by the government. Once again the Court disagreed. Because Part D *"certification"* required CVS Caremark's *"acknowledgement that the data will be used for the purposes of obtaining Federal reimbursement", "It is irrelevant that MCS, not Defendants, received the initial payment from CMS." ..."Although CMS provides prospective payments to the Part D sponsor, who in turn prospectively pays the PBM, the PDE records are prerequisites to obtaining additional payments and to reconcile the accuracy of any previous payments made. Thus, because submission of a PDE is a condition of any future payment, a PDE is a claim or demand for payment under the FCA."* In the Relator's view, the clear FCA liability of PBMs and other subcontractors in Part D establishes the culpability of the PBM Defendants in this complaint, regardless of any attempts to shield themselves via domiciling plan functions (sponsor, PBM and specialty pharmacy) into separate legal entities.

191. The Court in *Spay* refuted another defendant argument that has important implication in this complaint. In its Motion to Dismiss, CVS Caremark contended that the Plaintiff did not plead with particularity that any costs the defendant allegedly reported in the PDE data were not the costs that the injured party (MCS, Medical Card System in Spay) actually paid. However, the Court concluded that: *"Whether Defendant actually paid out the claims, however, is irrelevant. The key question is whether Defendants <u>should have</u> paid those claims and submitted them to CMS, ultimately causing MCS to fail to return overpayments to CMS."* In this current Qui Tam filing, the Relator does not allege that inaccurate Manufacturer Defendants MS prices were submitted for payment to CMS in PDE reports. Rather, based upon fraudulent BFSFs and related price collusive between the Manufacturer and PBM Defendants, fraudulently escalated *"negotiated prices"* and related cost data were submitted to CMS in a myriad of PDE reports since the start of Medicare Part D.

192. In *Spay*, the Defendant attempted to separate the FCA exposure of the individual 37 data fields of the PDE report that is required to be submitted with each and every drug prescription in the Part D program. The Defendant alleged that PDE data fields that were not directly related to drug payment, such as patient ID information, would not qualify for claims status under the FCA. In sighting the CMS Instructions, including Sections 1.1 and 2, the Court disagreed: *"Finally, Section 2 goes on to list the thirty-seven data elements "that <u>must</u> be submitted on PDE records <u>for payment</u>. In light of such materials, it becomes abundantly obvious that, contrary to Defendants' belief, 42 C.F.R. x 423.505(k)(1)'s reference to "data related to payment" includes all thirty-seven data fields on a PDE record. This is, of course, not to say that such data fields are "conditions of payment", such that submission of these records with incomplete or inaccurate data automatically gives rise to a violation of the False Claims Act. Rather, it is the act of*

certifying the truth, accuracy and completeness of these fields under x 423.505(k)(1) & (3) when such data is not actually truthful, accurate or complete, that gives rise to the False Claims Act cause of action.

193. The Relator alleges that all of the PDE data fields regarding drug costs and reimbursement include significant false claims, since they are all predicated on fraudulently escalated MS *"negotiated prices"* due to fraudulent BFSF-related price collusion between the Manufacturer and PBM Defendants. In **Exhibit 36**, the nine key PDE data fields most directly implicated in the current alleged fraud are listed; namely Fields 26 (Catastrophic Coverage Code), 27 (Ingredient Cost Paid), 30 (Gross Drug Cost Below Out-of-Pocket Threshold, 31 (Gross Drug Cost Above Out-of-Pocket Threshold, 32 (Patient Pay Amount), 33 (Other True Out-of-Pocket (TrOOP) Amount, Low-Income Cost-Sharing Subsidy Amount, 35 (Patient Liability Reduction to Other Payer Amount, and 36 (Covered D Plan Amount. In the **Exhibit 36**, the Relator has provided the CMS description of the individual PDE Field data, as well as his view on its role in the fraud. In the current alleged fraud, the Relator alleges that virtually all the false claims in the other eight data fields stem from the initial excessive Manufacturer Defendants MS drug price inputted in Field 27 (Ingredient Cost Paid) due to the fraudulent *"negotiated price"*. The initial collusive and fraudulent MS drug price level then fuels cascading fraudulent PDE data submissions by the PBM Defendants related to Out-of-Pocket beneficiary spending limits, Catastrophic coverage, LIS Subsidies, TrOOP contributions and Patient Pay Amounts. As discussed previously, the Relator believes the PBM Defendants accounting of its 15% non-LIS Catastrophic cost-sharing requirements may be a key area for fraud detection. However, it appears that uncovering the details of this fraud pathway will require investigation of internal corporate transactions since the PDE submissions do not require specific disclosure.

DETAILS REGARDING THE ALLEGED STATE FALSE CLAIMS VIOLATIONS

194. In 2006, the first year of Medicare Part D, 5.7 million State *"dual eligibles"* accounted for 69% of the 8.3 million Low-Income Subsidy (LIS) beneficiaries. In turn, the LIS population accounted for 29% of overall Part D enrollment in 2006. See **Exhibit 10**. In subsequent program years, the growth of State *"dual eligibles"* has been modestly slower than the rest of the LIS population. In 2012, 6.9 million State *"dual eligibles"* accounted for 63% of the entire 11.0 million LIS Part D population. The overall LIS share of Part D enrollment has remained stable throughout the history of the program, accounting for 29% of the overall beneficiaries in 2012, as well. Regardless of these modest shifts, State *"dual eligibles"* comprise the largest proportion of the Part D LIS population.

195. In Medicare Part D, each State is responsible for funding a portion of the drug costs of their *"dual eligible"* beneficiaries (i.e., low-income elderly and disabled individuals who qualify for both

Medicaid and Medicare benefits) whose drug benefit was transferred from Medicaid to Medicare Part D as part of the MMA legislation. These State *"dual eligibles"* (typically people in poor health, with severe chronic diseases) account for the majority of Part D Low-Income Subsidy (LIS) beneficiaries who, in turn, account for more than 70% of high-price specialty drug spending in the program.

196. Via mandatory monthly transfers, known as *"Phase Down"* or *"Clawback"* payments, the States cover 35-40% of Part D LIS Subsidy Costs each year of the Part D program, with the exception of 2010 and the first half of 2011 when the Federal government provided additional State financial support as part of the American Recovery and Reinvestment Act of 2009 (ARRA). Since the inception of Part D, the annual total State *"Clawback"* payments have increased 53% from $5.5 billion in 2006 to $8.4 billion in 2012, with cumulative State payments of $46.6 billion through 2012. Not surprisingly, the State financial responsibility has risen directly in proportion to overall Part D LIS Subsidy costs, which rose 50% from $15.1 billion in 2006 to $22.6 billion in 2012. See **Exhibit 10**.

197. Central to the State false claims violations alleged in this complaint, the Part D *"Clawback"* payments are mandated and calculated by the Federal government, with the States having no option to decline participation. Furthermore, while *"Clawback"* payments are 100% funded through State *"General Funds"*, the payments are *"guaranteed"* by Federal matching Medicaid contributions. As such, if a State is delinquent with its *"Clawback"* payments, *"all unpaid amounts plus interest will be offset against Federal matching Medicaid payments that States otherwise receive during the quarter in which the "Clawback" payment is due." The Medicare Part D Low-Income Subsidy Program, Kaiser Family Foundation, September 2010.*

198. The unusual method of calculating the *"Clawback"* payments also has important financial implications for the States collectively and individually. The monthly *"Clawback"* payment for each State is calculated according to the number of *"dual eligibles"*, the per-capita expenditures (PCE) on prescription drugs covered by Part D for those *"dual eligibles"* and a *"phase down"* percentage (which declines from 90% in 2006 to 75% in 2015 and thereafter). See **Exhibit 37**. The per-capita growth for the *"Clawback"* calculations is based upon the national growth rate in drug spending, not trends in a particular State. In addition, the base level of *"dual eligible"* drug spending for any individual state was *"frozen"* at 2003 levels, with no opportunity for re-adjustment. As such, given the highly variable nature of drug benefits in Medicaid, States with generous benefits in 2003 were locked into these high-spending levels in perpetuity in Part D, with no opportunity for local cost control efforts. In fact, the only way that States can influence required Part D *"Clawback"* payments is via *"dual eligible"* enrollment levels. However, the State opportunity to influence enrollment is also relatively limited because much of the effort to increase Part D participation has been driven by Federal efforts since the start of the program. Overall, under Part D, the

States face escalating non-recourse *"dual eligible"* drug costs, which has been primarily driven by accelerating specialty drug spending.

199. According to Federal National Health Expenditure (NHE) data, Part D *"Clawback"* payments have accounted for all the increased State government spending for drug benefits since the 2006 start of Medicare Part D. As indicated in **Exhibit 38**, State and Federal spending for drugs in Medicaid in 2011 was virtually identical to 2006 spending levels in the $19.0 billion range. Notably, the Federal and State contributions to Medicaid drug spending have also been stagnant in the $10.8 billion and $8.1 billion range, respectively, in both 2006 and 2011. With Medicaid enrollment up 17% over this period, there has been a 15% decrease in drug spending per Medicaid beneficiary, from approximately $493/person/year to $420/person/year, during the first six years of the Medicare Part D program.

200. In contrast, Part D State *"Clawback"* payments increased by 29% from $5.5 billion in 2006 to $7.1 billion in 2011, will the latter number artificially deflated by additional Federal contributions in the first half of 2011 as part of the ARRA. Of note, $4.3 billion in additional Federal funding to *"Clawbacks"* was disclosed for 2010. However, the Relator has not been able to locate public disclosure regarding the proportion of the additional $22.5 billion in Federal assistance for Medicaid that was specifically targeted for Part D State assistance in 2011. In Part D, the LIS Subsidy per LIS enrollee increased by 14% over the same timeframe, from $1,817/person/year in 2006 to $2,104/person/year in 2011. See **Exhibit 5**.

201. While the *"dual eligibles"* in Part D are far sicker than typical Medicaid beneficiaries and have far higher drug cost needs, the sharp divergence in spending by beneficiary is notable for a few reasons. First, both Medicaid and Medicare beneficiaries have benefited financially from the large number of traditional pharmaceutical patent expirations since the start of Part D. However, with the manufacturer benefit from price inflation limited to CPI-U since 1991 by the Medicaid legislation, the severe MS specialty drug inflation outlined in this complaint had a minor impact on State Medicaid specialty drug spending. As noted previously, the Relator has determined that the Manufacturer Defendants MS drugs are currently available at 80-90% discounts to the prices in Medicare Part D. In contrast, the States have borne the cost of the severe price inflation for the drug treatment of its *"dual eligible"* MS population since Part D places no limit on price increases. Since the MS drug category is a top-spending therapeutic area in Part D, the States have no doubt been defrauded of considerable monies via excess required Part D *"Clawback"* payments related to the alleged collusive pricing scheme.

202. Pertaining to this Qui Tam case, the legislative history of the *"Clawback"* payments is worth discussing, since it represented an unusual exertion of Federal authority over States. According to documents reviewed by the Relator, the *"clawback was an eleventh-hour addition to the MMA inserted in an attempt to*

address Part D's significant budget overrun". The clawback did not appear in either the House or Senate bill. Neither bill required dual eligibles to switch drug coverage from state Medicaid plans to the new Medicare benefit. The Senate bill, in fact, required dual eligibles to continue receiving their prescription drug coverage through state Medicaid plans. The House bill gave these beneficiaries the option to enroll in Part D and remain enrolled in the Medicaid drug plan; Part D would be primary and Medicaid would be "wrap around" coverage. Cooperative Federalism and Healthcare Reform: The Medicare Part D "Clawback" Example, Elizabeth A. Weeks, St. Louis University Journal of Law and Policy, Vol 1, Issue 1, 2007. However, apparently with little legislative discussion, the *"Conference Committee"* late in the process added the *"Clawback" payments*, permanently requiring States to bear a portion of the Federal Budget for Part D.

203. In 2006, due to budgetary impact and State sovereignty concerns, five States (Texas, Kentucky, Maine, Missouri and New Jersey) sought direct review of the *"Clawback"* by the Supreme Court. Several other States (Arizona, Alaska, Connecticut, Kansas, Mississippi, New Hampshire, Ohio, Oklahoma, South Carolina and Vermont) filed an amicus brief in support of the case. The States argued that the *"clawback raises serious constitutional questions regarding Federal intrusion into essential State functions, namely, the budgetary process."* However, not unexpectedly, on June 19, 2006, the Supreme Court declined to review the case before its pursuit in lower courts. Although significant constitutional issues regard the *"Clawback"* persist, no State has ever brought the case to lower courts, and the budgetary impact of the payments turned out not to be as great as anticipated. As will be discussed later in more detail, in the Relator's estimation, the over-estimation of Part D costs before its enactment by the Congressional Budget Office (CBO) has been an important factor deflecting scrutiny of the severe specialty drug price inflation described in this case.

204. With a direct tie between *"Clawback"* payments and Federal Medicaid matching payments, the State Medicaid FCA liability of both the Manufacturer and PBM Defendants seems clear in this current case. However, other factors related to the operation of Part D also appear to heighten State FCA liability in this case. First, despite the Federal government having near full control of the program, State Medicaid programs play a central role regarding the enrollment and administration of Part D. In fact, Medicaid apparently bears 75-90% of Part D administration costs. *Weeks, Id.* Second, for most *"dual eligibles"*, Part D premium subsidies are provided via their Medicaid insurance. Third, most State also have State Pharmacy Assistance Programs (SPAPs) that commonly provide financial support for *"dual eligible"* drug costs.

205. Finally, CMS has severely restricted the ability of State's to detect fraud by limiting their access to Part D PDE data. As discussed previously, between 2006 and 2008, no PDE data was available to parties outside the Federal government. However, starting in 2008, States and other entities have been able to request PDE data from CMS on a limited basis. In a CMCS Informational bulletin dated May 11, 2011, CMS

further expanded State access to PDE data for "*care coordination activities*". *CMCS Informational Bulletin, Subject: Access to Medicare Data to Coordinate Care for Dual Eligible Beneficiaries, May 11, 2011.* However, based upon *42 CFR 423.505(m)*, which includes privacy protections of the data, CMS has kept the PDE disclosures to States very limited. For instance, CMS *"determined that financial data elements will not be made available."* CMS also stated in the bulletin: *"Finally, please note that these data will not be permitted to be used by the State Medicaid Agency, nor matched with files from other State agencies, for any purpose other than care coordination for dual eligible beneficiaries, e.g., investigating fraud or conducting research."*

BASIS FOR THE RELATOR'S INVESTIGATION

206. The initial catalyst of the Relator's investigation leading to this complaint was his inability to comprehend the factors behind massive price inflation in the US multiple sclerosis drug category. The severe price inflation was incongruous with his extensive clinical knowledge of the therapeutic area, as well his previous first-hand analytical experience as a professional pharmaceutical equity analyst tracking highly-successful *"therapeutic substitution"* tactics utilized by PBMs. The Relator, employed as a dedicated healthcare analyst/portfolio manager for more than 22 years, has been tracking in great detail all aspects of the multiple sclerosis drug therapy market, starting prior to the availability of the Manufacturer Defendants drugs targeted in this complaint and continuing to the present day. Based upon this extensive knowledge and experience, the Relator knew that the highly-concentrated PBM industry was capable of garnering significant discounts for their clients (plan sponsors) from the Manufacturer Defendants since the MS category was mature, crowded with long-standing similar products and subject to intense competition from new product introductions. However, despite these severe competitive pressures, systemic massive US price inflation of an unprecedented magnitude for all of the Manufacturer Defendants' MS drugs was and is occurring nonetheless.

207. All four of the long-standing Defendants' MS drugs, Biogen's Avonex (US approval; May 17, 1996), Teva's Copaxone (US approval; December 20, 1996), Bayer's Betaseron (US approval; July 23, 1993) and EMD Serono/Pfizer's Rebif (US approval; March 7, 2002) have been available in the US market for more than a decade. In 2009, Novartis' Extavia (identical molecule to Bayer's Betaseron) was also launched in the US. While there have been modest FDA label updates for each of the Manufacturer Defendants MS drugs since initial approvals, the well-established clinical profiles of these long-marketed MS drugs has remained relatively constant since the 2006 start of Medicare Part D. Regardless of modest safety/efficacy/mode of delivery differences, the Relator has long been aware, from his own clinical and market analysis, as well as from neurologist physician expert conversations, that these long-standing therapies are considered largely clinically *"interchangeable"* for the majority of multiple sclerosis patients with the most common relapsing form of the disease. In fact, the long-established similar role of these older agents is clearly indicated in the

treatment guidelines (which have not been updated since 2002) from the leading US MS physician organization, the American Academy of Neurology (AAN), which is also endorsed by the Consortium of MS centers. *Goodin, EM, Frohman, et. al., Neurology 2002;58; 169-178, "Disease modifying therapies in multiple sclerosis".* According to the AAN guidelines, all beta-interferons (Avonex, Rebif, Betaseron/Extavia) and glatiramer acetate (Copaxone) sold by the Defendants have been shown to "*reduce the attack rate"* and are *"appropriate to consider for any patient with relapsing remitting multiple sclerosis"*. Furthermore, the treatment guidelines from the National Multiple Sclerosis Society, the largest US MS treatment and patient advocacy organization, also offer no significant distinction between the five drugs. *Expert Opinion Paper; National Clinical Advisory Board of the National Multiple Sclerosis Society, Treatment Recommendations for Physicians.*

208. The Manufacturer Defendants' MS drugs have also faced a significant challenge from new MS therapies that have entered the US market in recent years. Major recent new US MS therapies include Biogen/Elan's Tysabri (US approval 2005), Novartis' Gilenya (2010), Sanofi's Aubagio (2012) and Biogen's Tecfidara (2013). The Manufacturer Defendants' MS therapies have experienced a significant decrease in patient usage and related market share due to the clinical advantages of the new therapies. First, while Gilenya, Aubagio and Tecfidara all carry the same broad MS label as the older injectable agents, as oral therapies they are often easier for patients to use. Second, the FDA-approved label for Gilenya includes clinical data demonstrating efficacy superior to Biogen's Avonex; a head to head trial determined that Gilenya decreased the annualized MS relapse rate by approximately 50% and the relative risk of disability progression by about 29%. Aubagio offers efficacy similar to the older MS agents, but is perceived by many physicians to be more convenient and tolerable. Finally, while not reflected in the approved label, Tecfidara is considered by many neurologists to offer superior efficacy, convenience and safety compared to the Manufacturer Defendants' older products. The favorable clinical profile of Tecfidara has fueled its meteoric uptake in the US following its launch in late March 2013.

209. With the severe new drug competition, especially from new oral entrants, usage of the Manufacturer Defendants older MS drugs has been in significant decline in recent years. By the Relator's estimation, the number of commercial insurance/Part D US patients treated with the Defendant MS drugs declined from about 188,000 in 2005 to the 149,000 range in 2012, representing approximately a 21% decline over the period. See **Exhibit 3**. As such, the US market share of the four long-marketed Defendant MS drugs fell from 100% in 2005 to the 78% range by the end of 2012. Despite this severe erosion in use and counter to any competitive market rationale, the average annual US cost of therapy per patient for the four long-marketed Manufacturer Defendant MS drugs rose from about $12,000 in 2005 to the $41,000 range in 2012. However, as discussed earlier in the complaint, the signs of price collusion in the US MS category have accelerated even further in 2013 following the launch of Biogen's new oral therapy, Tecfidara. With Tecfidara rapidly taking

market share primarily from the older Defendant MS drugs, their usage has declined approximately another 22% just in 2013. See **Exhibit 4**. The Relator estimates that cumulatively the US usage of the older injectable Manufacturer Defendants MS drugs is down approximately 35-40% between 2006 and 2013. However, despite the accelerating erosion in usage, combined US sales of the Defendants' older MS drugs actually increased approximately 8% in 2013 due to a further acceleration in already severe price inflation. See **Exhibit 3**. Following a series of significant price increases for all four long-standing Defendant MS drugs, the annual US cost of therapy has risen from the $41,000 range in 2012 to nearly $59,000 (before manufacturer rebates/discounts) by December 2013.

210. Other clinical and competitive factors should also make the US MS category amenable to aggressive branded *"therapeutic substitution"* techniques that the PBM industry has employed with great success in the past in traditional pharmaceutical therapeutic categories. First, MS represents a high cost specialty drug spending category for virtually all commercial and Part D plans in the nation. As mentioned previously, the MS category was the leading driver of increased specialty drug spending at Express Scripts in recent years. In the Express Scripts clientele, which is highly representative of the broader market, MS drugs accounted for the largest share of overall Part D specialty drug spending, by a wide margin in each of the past three years. See **Exhibits 18 & 19.** With these trends, the MS drug category has been very costly for the majority of PBM clients and a major source of concern.

211. Second, compared to other specialty areas, the treatment of MS is usually less complex, with drug therapy accounting for the vast majority of the cost of treating patients. Because most MS patients have the typically stable relapsing variety, exacerbations and expensive acute interventions are infrequent. In contrast, medical complications can greatly increase the cost of care in other specialty areas, especially cancer. As support, a recent MS economic study indicated that drugs accounted for 72-84% of the cost of treating MS patients. Not surprisingly, the study also concluded that *"cost savings in the medical component (of MS care) did not offset the increased pharmacy expenditures (due to extreme drug price increases) during the 12-month follow-up period*" between 2004 and 2008. *Tan, H, et. al, Clinical and Economic Impact of a Specialty Care Management Program among Patients with Multiple Sclerosis; A Cohort Study; MultScler, 2010, August; 16(8): 956-963.* Finally, unlike many other specialty drugs, the Manufacturer Defendants' older MS drugs are self-administered injections at home that are taken chronically and don't require significant monitoring once patients are stable.

212. As mentioned previously, with these characteristics, 90% of MS drug use is managed through the pharmacy benefit, controlled primarily by PBMs in Medicare Part D. With these parameters, in a proper functioning competitive market, the dominant PBM Defendants should have plenty of motivation and leverage to negotiate significant price concessions from the Manufacturer Defendants for their clients. Despite market

dynamics indicating a strong motivation and opportunity for MS cost savings, spending on these older MS agents has accelerated due to unprecedented price inflation and collusion between the Manufacturer and PBM Defendants.

213. The minimal impact of Novartis' Extavia in the US marketplace is also highly indicative of market collusion. In August 2009, Novartis received FDA approval for Extavia, a branded version of interferon beta-1b for the treatment of relapsing forms of multiple sclerosis. Extavia is identical to Bayer's Betaseron; the products share the same FDA approved clinical label. Novartis gained the rights to market its own version of the same molecule in the US as part of a 2007 deal in which Bayer acquired Novartis' US biologics manufacturing facility in Emeryville, CA, which is where Betaferon was and presumably still is manufactured. Given the identical products and the crowded US MS marketplace, one might have anticipated an intense market share and pricing battle between Bayer and Novartis, especially given the dominant leverage of the PBM Defendants.

214. In reality, the impact of Extavia on the US MS market has been minimal. Based upon public prescription share and pricing data, the Relator estimates US Extavia sales of less than $10 million in 2009, rising only modestly to the $35 million range in 2013. In contrast, despite severe volume erosion due to other competitive factors, estimated US Betaseron sales have remained above $600 million per year due to massive price increases for the product. Furthermore, while Extavia was initially priced at a modest discount to Betaseron in the US, the cost for both drugs has escalated considerably in recent years. Extavia's annual cost per US patient is now in the $50,000 per year range. Of course, given the modest US sales for Extavia, any direct BFSF fraud and related revenues would be minimal as pertains to this case. However, Novartis's failure to effectively compete with Extavia likely reflects the company's primary focus in the MS space on its high potential oral therapy, Gilenya, which launched in the US in 2010. It would obviously be to Novartis' advantage to avoid MS category price competition in order to maximize the price and revenues of Gilenya. Of note, Gilenya was launched in 2010 at a cost of $42,000 per patient per year; at the time, a modest premium to the older injectable drugs. However, after aggressive price increase, the annual cost of Gilenya approaches $60,000 per year; at present, among the highest cost MS therapy in the US market.

215. The Manufacturer Defendants themselves have commented sparingly regarding the severe MS drug price inflation, more than likely in order to avoid public scrutiny. For example, Biogen and Teva have largely limited their public remarks to statements such as, the price of the drug is *"consistent with the real-world value it delivers to patients"* and the drugs are priced *"competitively"*. *New York Times article, July 20, 2011.* However, investors and other constituents are increasingly seeking management feedback as high specialty drug prices have become a greater public issue.

216. More recent commentary from a Biogen senior executive, which was firsthand witnessed by the Relator, indicates potential willful deceit regarding the causes of severe US MS drug price inflation. On Monday, February 24, 2014, Tony Kingsley, the Executive Vice President of Global Commercial Operations at Biogen, participated in a panel discussion at the annual Citigroup Healthcare Conference. When an audience member asked Mr. Kingsley to comment regarding factors behind severe US MS drug price inflation, the executive stated that price control tactics have not been not effective in the US MS market because the clinical *"outcome measures"* for MS were *"not well-defined"*. This statement by Mr. Kingsley is simply factually incorrect, as anyone with a modest knowledge regarding clinical measures for MS drugs is well-aware.

217. In **Exhibit 39**, the Relator has provided key summary data from the FDA-approved labels for both the Manufacturer Defendants drugs and other key MS drugs approved for the treatment of relapsing MS. As per the FDA approved labels, the clinical *"outcome measures"* required for FDA approval as a treatment of relapsing MS have been IDENTICAL for every drug developed for the disease since the first one, Betaseron, was approved in 1993. All relapsing MS drugs, including the older injectable agents and newer oral therapies, have been approved on the basis of the same three outcome measures; namely the drug's impact on *"disability", "multiple sclerosis exacerbations"* and *"brain lesions measured by MRI"* (magnetic resonance imaging). Furthermore, according to FDA-approved clinical data, only two products, Pfizer's Rebif and Novartis' Gilenya, can make any claims regarding potential clinical superiority over other relapsing MS therapies. High-dose Rebif demonstrated a modest decrease in MS exacerbations (i.e., relapses) compared to Biogen's Avonex, but with significantly more side effects. Gilenya's clinical superior claims compared to Avonex was discussed previously. However, Gilenya also has safety trade-offs due to potential rare severe cardiac toxicities. In reality, the unchanged clinical outcome measures in the MS category stand in sharp contrast to many other medical areas, such as cancer, in which outcome measures have shifted dramatically and frequently over the past several decades. With numerous MS therapies with nearly identical FDA approved indications and outcome data, the opportunity for payer negotiating leverage in the high-cost US MS category since the start of the Medicare Part D program has been considerable. The PBM Defendants have had the capability to prevent significant price inflation, and to likely obtain price cuts for the long-standing Manufacturer Defendants MS drugs in declining use. Unfortunately, the PBM Defendants decided to use their dominant market position instead in a collusive pricing scheme with the Manufacturer Defendants to reap massive fraudulent financial gain at the expense of elderly beneficiaries and the American taxpayer.

218. The *"interchangeability"* and *"substitutability"* of the older Manufacturer Defendants MS drugs was recently verified by an unprecedented policy change at Express Scripts, the largest PBM in US. In October 2013, Express Scripts announced that Bayer's Betaseron would no longer be available in its National Preferred Formulary starting in 2014, the first time that one of the Manufacturer Defendants' MS agents has been excluded by the nation's largest PBM. Of note, Express Scripts' National Formulary is used verbatim by 30%

of the 100 million people whose drug benefit is managed by the PBM. In addition, for many other Express Scripts clients/beneficiaries, the National Formulary is the starting point in plan design. In public commentary discussing its rationale, Express Scripts cited *"therapeutic interchangeability"* and *"rapid price increases"* as key reasons for the policy change. However, consistent with past disclosures, Express Scripts denied that its organization has played any role in the massive US price inflation of Betaseron or other specialty drugs in recent years. Of note, in the company's third quarter 2013 conference call on October 25, 2013, Express Script's Chief Medical Officer (CMO), Steven Miller admitted the watershed nature of these formulary changes as pertains to specialty drugs, such as those used in the MS area. In response to a question from a Wall Street analyst, he stated *"One of the really exciting points to this formulary change, as you know, is we actually excluded drugs inside specialty categories. This is really unprecedented in the industry"*.

219. A press interview with Mr. Miller related to the Express Script's formulary changes verifies the Relator's assessment of the true underlying nature of competitive dynamics in the US MS drug market, as well as numerous other specialty drug therapeutic categories. In an interview with Pharmalot (a website targeted at pharmaceutical executives), published on October 17, 2013, Mr. Miller stated that *"85 percent of drugs (in Express Script's National Formulary) are clinical optional - where outcomes data demonstrates other drugs are equally well suited"*. As indicated by the Relator's clinical assessment, nowhere is this statement more accurate than for the Defendants' five MS drugs at the center of this complaint. All the Manufacturer Defendants' MS drugs (Extavia is the same as Betaseron) have been on the US market for 10-20 years and have nearly identical FDA-approved clinical benefits.

220. While Express Script's exclusion of Betaseron and a small number of other therapies for the first time suggests long-awaited US specialty drug competition is on the rise, the PBM admits that the changes thus far are quite modest. According to Mr. Miller, the 48 drugs excluded starting in 2014 will only impact about *"2.6% (780,000) of the 30 million people who have their benefit on the national preferred formulary"* and *only "represent about 1 percent of the drugs on the formulary"*. The impact on the entire *"almost 100 million people"* whose drug benefit is managed by Express Scripts is even more modest.

221. However, despite the small number of drugs and beneficiaries affected by the 2014 Express Scripts formulary changes, Mr. Miller also stated during the same conference call that *"these changes result in over $700 million in annual savings for our clients on the national preferred formulary"*. These significant savings, for even small formulary changes, clearly indicate the magnitude of potential savings to CMS and taxpayers from properly functioning manufacturer/PBM competitive relationships, especially considering the massive price inflation in the crowded MS and other specialty categories in recent years.

222. As supported by the Relator's investigation and Express Script management commentary, these modest initial PBM formulary changes regarding specialty drugs are finally occurring due to increased pressure from clients. With specialty drug spending having risen consistently 20-25% annually (primarily driven by price inflation, not volume growth) for at least the past 5-7 years at virtually all commercial and Part D plans managed by PBMs, the segment now accounts for approximately 25% of overall US drugs spending compared to only about 17.5% in 2004. As such, PBM client focus on specialty drugs has increased dramatically in recent years. Unfortunately, the Relator alleges that massive, collusive price inflation related to BFSF fraud has already occurred for the Manufacturer Defendants MS agents in the initial seven years of the Medicare Part D program.

FAIR MARKET VALUE OF BONA FIDE SERVICE FEE BACKGROUND

223. With CMS purposely not defining methods for BFSF FMV assessment in the Part D program, each manufacturer must determine its own process based upon acceptable practices in the private marketplace. Although FMV assessment in the business world is designed to provide flexibility, an extensive review of the area reveals remarkable consistency in recommended approaches across both private and government entities. The definition of FMV provided by the American Society of Appraisers has been generally accepted by both private industry and government agencies: *"The price expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts". American Society of Appraisers Business Valuation Standard Glossary, Approved June 2005, Copyright 2005, American Society of Appraisers.*

224. In the private sector, generally accepted valuation principles employee three primary approaches to FMV assessment: the *"Income"*, *"Market"* or *"Cost"* Approaches. Using the *"Income Approach*", the FMV payment would be based upon the amount and timing of cash flows generated by the business, asset or service. The *"Income Approach"* is typically not relevant in services provided by healthcare professionals (i.e., including PBM service agreements with manufacturers) because "*these services cannot, and should not be, directly associated with cash flow." Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.* As such, the Relator's review indicates that use of the *"Income Approach"* is not appropriate for most of the supportive (rather than income generating) services provided for manufacturers by PBMs/specialty pharmacies within Medicare Part D under typical service agreements. This conclusion was verified by presentations and commentary at the October 7-8, 2013 FMV BFSF conference discussed in the next section of the complaint.

225. In the *"Market Approach"*, FMV is determined by looking at the market prices of similar services. As such, within Medicare Part D, a manufacturer may decide to determine the FMV of a service arrangement with a PBM/specialty pharmacy based upon the financial terms of competitor manufacturer/vendor relationships. However, this approach carries significant risk under the Anti-Kickback Statute. These concerns were summed up in a 1992 letter from the OIG to the IRS: *"Merely because another buyer may be willing to pay a particular price is not sufficient to render the price to be paid fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase." Letter from D. McCarty Thorton, Associate General Counsel, Office of Inspector General (HHS) to T. J. Sullivan, Technical Assistant, off of the Associate Chief Counsel, Employee Benefits and Exempt Organizations, December 22, 1992*. The Anti-Kickback Statute further states, *"If compensation is based upon comparables, assurance is required that the markets are not "distorted" and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". OIG Supplemental Compliance Program for Hospitals, p 4866-67.* Highly relevant to this Part D Qui Tam case, the Anti-Kickback Statute also cautions that FMV carries a risk of fraud if there are *"direct or indirect ties between compensation and Federal healthcare program reimbursement." 42 U.S.C. §1320a-7b(b)*

226. The use of external FMV consultants, a common industry practice, does not protect manufacturers from fraud risk exposure. According to the American Health Lawyers Association, *"Parties should also carefully recognize the fact that commercial reasonableness is often outside the scope of most expert opinions of fair market value, insofar as many internal and outside appraisers do not have sufficient qualifications or information about the transaction to make an informed business judgment regarding its commercial reasonableness without a separate and detailed inquiry into the business (and often clinical) aspects of the transaction or contractual arrangement." Gregory D. Anderson CPS/ABV, CVA Horne LLP, Fair Market Value: What's Fair and is it Commercially Reasonable?, American Health Lawyers Association Annual Meeting, June 27-29, 2011.* Based upon his investigation and public commentary, the Relator concluded that most external FMV and legal experts likely lack the clinical expertise to properly assess the competitive dynamics in the US MS specialty drug marketplace. Given these legal concerns, healthcare FMV consultants typically suggest that *"companies should not rely on payments made by their competitors in the industry as they may not represent fair market value. Rather, I estimate a market rate using the market compensation for individuals with the qualifications needed to perform the services, adjusted to reflect a consulting rate by adding overhead costs and profit.*" This quote came from a 2012 article by Navigant Life Sciences, a leading FMV consultant serving the pharmaceutical industry. *Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012*

227. In the *"Cost Approach"*, the FMV of the service is based upon the cost of providing the service, plus a reasonable profit. In this methodology, the FMV should not exceed the cost to obtain substitute service from a third-party in an *"arm's-length"* transaction. In this approach, certain estimates are required but have the potential to be more accurate than provided by the Income or Market methods. Extensive investigation and direct expert commentary clearly indicate that the straightforward *"Cost Approach"* is the most appropriate and accurate way to assess the FMV of service fees paid by manufacturers to PBMs and specialty pharmacies in the Medicare Part D program. First, FMV experts clearly state that FMV payments should be determined for a *"service and not a person"*, as quoted from the Navigant Consulting article cited above. In a September 2012 presentation, consultants from Huron Associates stated: *"Once a fair market value range for an activity is determined, the amount should be multiplied by the volume of that activity for each type of service and added together to arrive at a fair market value range for the contract." Huron Life Sciences Presentation, "Determining the Bona Fide Nature of Fee-for-Service Arrangements", 9/27/12.*

228. Huron Life Sciences further verified that the *"Cost Approach"* is the preferred methodology for valuing *"bona fide"* services. In a slide from the same presentation cited above, Huron states that the *"price for a bona fide service"* can be thought of as an amount that covers:

a) the direct cost of the service;

b) the overhead associated with delivering that service;

c) the cost of assets used up in the delivery of the service; and,

d) a reasonable return on the assets employed in the delivery of that service".

229. Of note, a review of standard financial practices regarding the *"Cost Approach"* indicates acceptable *"rate of returns"* in the 10-15% range for *"arm's length transactions"* across numerous industries. As discussed in this complaint, the Relator's analysis estimates that annual fee payments per treated patient from the Manufacturer Defendants to the PBM Defendants have increased nearly five-fold in 2013 compared to just prior to the start of Medicare Part D, despite a significant decline in patient usage. In the Relator's view, these payments are far in excess of a *"reasonable rate of return"*, representing a fraudulent FMV assessment.

EVIDENCE OF FRAUDULENT MANUFACTURER/PBM SERVICE CONTRACTS

A. Relator's Review of Esoteric Public Documents

230. The fraudulent nature of manufacturer/Service Vendor *"Market Approach/Percent of Revenue"* fee relationships was initially identified by the Relator through an investigation of esoteric public documents. First, in a February 15, 2013 article in Specialty Pharmacy Times entitled, *"Why We Care about Bona Fide*

Service Fees?", Chris Coburn, a Senior Vice President of Commercial Business Strategies at Compliance Implementation Services (CIS, a leading BFSF consultant to drug manufacturers) discussed the quandary manufacturers face in properly valuing BFSFs. Mr. Coburn stated: "*The Proposed Rule for AMP (average manufacturer price) published by CMS at the end of January 2012 states that they will not define FMV and would put the burden on the manufacturer. This is difficult, as most of the service-type fees paid are based on a percentage of sales."*

231. Second, in the October 2006 issue of the Healthcare Savings Chronicle, Joseph Coffini, RPh, a Principal at Trivantage Pharmacy Strategies, Inc. (a pharmacy benefit and audit consulting firm run by two former Medco PBM executives, later acquired by Thomson Reuters in 2009), discussed the details of PBM contracts. Mr. Coffini stated*: "The second PBM revenue channel is the Pharmaceutical Manufacturer. This comes in the form of rebates, manufacturer admin fees, data fees - all based on your drug spend."* Third, in the company blog on June 25, 2012, Rick Moore, another consultant from CIS, entered a post entitled, *"BFSF Blog Series Article #1: Potential Impact of Increased Distributor Service Fees on GP"* (government prices), in which he stated: "*Fees are ranging as high as 9%-12% of gross sales, which is actually down from 11-17% of gross sales from some manufacturers, subsequent to negotiations"*.

B. Relator's First-Hand Direct Quotes/Feedback from *"Insiders"* at the *"First Ever"* FMV of BFSF Conference

232. Although the Relator previously uncovered all aspects of the fraud via independent investigation, definitive confirmation of the scheme came from his attendance at a recent conference specifically focused on the topic at the center of this Qui Tam case. On October 7-8, 2013 in Philadelphia, PA, the Relator attended a two-day conference entitled, *"Fair Market Value of Bona Fide Service Fees"*, sponsored by CBI, a subsidiary of Advanstar, which describes itself as *"the leading provider of market-driven, unbiased conferences for the pharmaceutical, biotechnology, medical device and healthcare industries."* The full agenda for the conference can be obtained from CBI/Advanstar. In his welcoming remarks, Chairman of the conference, Tom Evegan, the Senior Director of Commercial Contracting from Compliance Implementation Services (CIS), a leading government compliance consulting firm serving drug manufacturers, stated that the event represented the *"first ever"* conference specifically focused on FMV of BFSFs. At the conference, the Relator obtained extensive evidence of the potentially fraudulent, industry-wide drug manufacturer practice of using *"Market Approach/Percent of Revenue*" service fee contracts, without adjustments for price increases, with Service Vendors. The definitive evidence came via direct commentary and quotes from senior manufacturer pricing staff, as well as senior legal advisors and FMV consultants servicing manufacturers in attendance at the conference. Of note, in the Relator's view, the *"tension"* in the room regarding escalating FMV BFSF fraud risk was *"palpable"* throughout the two-day conference. Although, as expected, the presenters were careful not

to disclose significant incriminating evidence in slides from their presentations, commentary and discussion provided clear evidence supporting the fraud allegations in this complaint.

233. The *"insider"* feedback from this *"first of its kind"* conference provides extensive support regarding the FMV BFSF fraud between the Manufacturer and PBM Defendants in the Medicare Part D program. Candid and incriminating evidence from an array of FMV and BFSF industry *"insiders*" at the conference is provided throughout this complaint.

234. All key components of the fraud were verified via presentations, candid discussions and direct quotes from senior manufacturer, legal and consulting professionals at the October FMV BFSF conference, namely:

a) *"Bona Fide Service Fees"*, rather than traditional discounts, have become the primary vehicle for manufacturer compensation of PBMs/specialty pharmacies in the Medicare Part D program;

b) The majority of *"services"* provided by Service Vendors (including PBMs/specialty pharmacies in the Medicare Part D) should be valued via the *"Cost Approach"* to FMV (i.e., typically using straightforward labor rate/time needed, tied to patient/volume usage), including for specialty therapies such as the multiple sclerosis drugs sold by the Manufacturer Defendants;

c) The standard contract terms between drug manufacturers and service vendors utilize *"Market Approach/Percent of Revenue"* terms, despite concerns about increased fraud risk.

d) *"Market Approach/Percent of Revenue"* service contracts tied to significant price increases must be adjusted over time (i.e., *"refreshed"*) in order to limit FMV legal risk;

e) However, *"Market Approach/Per cent of Revenue"* service contract adjustments for significant price increases (to maintain an appropriate FMV range) are rarely being done in the marketplace, primarily due to the considerable negotiating leverage of large Service Vendors (i.e., the dominant PBM Defendants in Medicare Part D) with drug manufacturers.

235. The October FMV BFSF conference was primarily attended by senior staff from biopharmaceutical manufacturers responsible for federal program compliance, as well as representatives from leading consulting and law firms that advise industry regarding BFSFs and FMV. In addition, executives from several leading PBMs were in attendance. Of particular note was the absence of CMS or any other government agencies at the conference.

236. While presenters and attendees at the October FMV BFSF conference were careful not to mention specific products or therapeutic areas, these standard industry service contract practices clearly apply to the multiple sclerosis and other specialty markets. First, the definitive feedback obtained by the Relator at the conference occurred while key senior staff from MS manufacturers and leading PBMs were in attendance. For instance, senior legal officials from Manufacturer Defendants Pfizer and Sanofi (marketer of Aubagio) were in attendance. In addition, a Director of Product Marketing from the Accredo Specialty Division of Defendant Express Scripts attended, as did the Vice President of Business Development and Industry Relations from Diplomat Specialty Pharmacy. The meeting also included representatives from other leading specialty manufacturers; namely Johnson & Johnson, Amgen, Glaxo, Novo Nordisk, Astellas, Abbvie, Gilead, Mylan, Bristol Myers and Otsuka.

237. The legal and consulting firms which provided most of the presentations and led much of the discussion at the FMV BFSF conference are among the largest and most influential firms with specific BFSF and FMV healthcare practices. Other than CIS, attendance from the consulting arena included representatives from Huron Consulting and Navigant Consulting. On the legal front, attendance included representatives from King & Spalding, Reed Smith, Hogan Lovells and Sidley Austin. Since these firms serve the majority of top pharmaceutical and biotechnology companies, numerous of them undoubtedly have direct involvement with the high-spending MS drug category and the Defendant manufacturers in this case. In addition, a Relator review found that representatives from the consulting and legal firms at the FMV BFSF conference have been mainstay presenters at virtually every conference regarding government drug pricing and compliance in recent years.

238. The Relator has assembled the name/title/phone contact information for presenters and attendees at the October FMV BFSF conference. This information is provided in **Exhibit 40**. This list includes most of the people at the conference, based upon the public agenda and a private poster on display at conference. The log may not include some late registrants and a few on the list may have cancelled their actual attendance. In addition, the Relator could not locate contact information for several attendees listed on the poster at the conference. A full list of attendees at the conference can be obtained from CBI/Advanstar.

239. As a central tenet of this Qui Tam case, it is alleged that, due to the unique financial incentives in the Medicare Part D program, manufacturers are highly-incented to compensate service providers (PBM and other Service Vendors) via undisclosed BFSFs rather than traditional discounts. Because BFSFs are excluded from government *"negotiated price"* calculations, their preferential use leads to higher revenues and profits for manufacturers and PBMs, at the expense of increased drug costs for CMS and its elderly Part D beneficiaries. This assessment was fully-supported by numerous statements during the October FMV BFSF conference. In fact, in just the first few minutes of his opening statements at the conference, Tom Evegan of CIS stated that

"fees were the key to government pricing" and the majority of compensation to service providers from manufacturers had *"shifted from rebates to fees"*. The central role of BFSFs for PBM compensation was further verified by Mark Dewyngaert, a leading FMV expert from Huron Consulting. During his presentation on the second day, Mr. Dewyngaert stated that *"service fee agreements"* accounted for a *"substantial pool of money"* and were the *"main source of income"*.

240. Throughout the two-day conference, the leading industry and external FMV experts repeatedly highlighted the escalating fraud risk associated with the standard manufacturer/PBM *"Percent of Revenue"* contracts, especially for products with significant price increases. In fact, all the key issues surrounding this issue were covered in considerable detail by the very first presenter of the conference, John Shakow of the law firm King & Spalding. Of note, Mr. Shakow disclosed that he is a defense lawyer in the active Streck case regarding service fees in the Medicaid program. After providing some background on the history of BFSFs and potential legal risks, Mr. Shakow stated that he was *"not a fan of the market approach"* and that manufacturers need to *"consider whether percent of sales can be consistent with FMV as prices rise"*. He stated that it was *"a lot easier to have a fixed fee per unit of service"*, which would make him *"less worried regarding the impact of price increases"*. Mr. Shakow went on to say that *"CMS has never said explicitly that percent of sales fees were not excludable"* (i.e., from government price calculations), but may be *"closer"* to doing so since these arrangements *"may bear no relation to the value of service unless (the service is) price-based"*. He expected that these *"per cent of revenue*" deals will be *"challenged in the future"*. In his comments, Mr. Shakow also emphasized that the manufacturer's handling of fees must be able to "*withstand review/auditing by an independent party, which can determine the same FMV*", as well as *"justify the FMV to an outside party brought in by the government"*. He stated that the government will *"look beyond the agreement and evaluate the true nature of the fees, via emails, communications, interviews and sworn testimony"* in its search for *"intent"*. Throughout the conference, numerous constituents emphasized the need to document and verify fees with vendors for appropriateness and FMV. Numerous experts emphasized the need for manufacturers to insist on *"audit rights"* in their service contracts, while also admitting little success with these requests.

241. In their presentation, Isabel P. Dunst, a partner at Hogan Lovells and Julie DeLong, the Director of Valuation and Financial Risk Management at Navigant Consulting, offered somewhat contrasting views regarding valuation methodologies. Ms. Dunst clearly stated that she *"did not recommend percent of sales"* contracts to her manufacturer clients, while Ms. DeLong indicated more flexibility. Ms. DeLong stated that she *"can value anything"* and was comfortable *"translating per unit fees to percentage of revenue"*. Near the end of her presentation, Ms. DeLong further indicated her flexibility in the handling of fees between manufacturers and specialty pharmacy service providers. She stated that *"some want to be paid in different ways"* and that she could *"translate FMV into a dollar amount per month or year, as well as a percent of revenues"*. Around the time of this discussion, Ms. Dunst stated that she hoped *"the conference was not being recorded"*.

242. Additional specific conference commentary highlighted the significant fraud risk associated with *"percent of revenue"* service contracts tied to significant price increases. Mr. Shakow of King & Spalding stated that manufacturers must *"consider whether percent of sales deals can be consistent with FMV as prices rise"*. He further stated that *"FMV is a snapshot of a moment in time and may need to be repeated to maintain validity"*. As indicated previously, later in the session he stated his preference for a *"fixed fee per unit of service"*, which made him *"less worried regarding the impact of price increases"*. In the first few minutes of her presentation, Stephanie Gilson, the J&J Chief Counsel admitted that *"per cent of WAC (Wholesale Acquisition Cost, i.e., price-based), deals are often not updated by manufacturers"*. In her presentation, Julie DeLong of Navigant also stated that the FMV was a *"snapshot in time"* and "*per cent of WAC"* deals had greater risk with fast rising prices. An audience member then asked about the proper FMV handling of fees for $100 versus a $1,000 bottle with the same number of pills. Ms. Dunst, of Hogan and Lovells, did not provide a direct reply to this query, instead saying that a *"real problem was developing with percent of revenue"* contracts. In the final presentation of the conference, Chris Jackson, the Corporate Attorney for Otsuka America Pharmaceuticals stated that *"multi-year deals based on the per cent of WAC"* must be *"refreshed"*.

243. The FMV expert consensus preference for the *"Cost Approach"* to FMV in assessing the majority of service fees was also definitively verified by commentary at the October FMV BFSF conference. Numerous presenters clearly stated that for the vast majority of services provided by Service Vendors, the *"Cost Approach"* is the most legally justifiable valuation methodology. For instance, in his discussion of contracting processes on the second day of the conference, John Moose of Huron Consulting stated that the *"business plan"* of the manufacturer/Service Vendor contract must recognize that *"most of the value of services comes from the connection with the patient"* and that a *"dollar amount per activity is the easiest to justify"*. Consistent with the Relator's prior analysis, the standard *"Cost Approach"* typically utilizes a *"rate grid"*, using a wage rate and time estimate to calculate FMV for a particular service. The *"rate grid"* cost approach was discussed in detail by two Johnson & Johnson government contracting executives, Michael Hepburn and Doris Chern, during their presentation on the first day of the conference.

244. More specific to the Manufacturer Defendants' MS drugs, at the conference Julie DeLong from Navigant Consulting, and Isabel P. Dunst from Hogan Lovells, discussed the topic of FMV approaches to specific services provided by specialty pharmacies. Of note, according to the Relator's investigation, this presentation was the first in the public domain specifically targeting the FMV of specialty pharmacy services. At the outset of the presentation, Ms. Dunst stated that *she "does not view the specialty channel any differently from other channels"* regarding the handling of fees and FMV. However, the presenters did state that separating *"core"* and *"non-core"* services for specialty pharmacies, compared to traditional distribution channels, can be difficult for manufacturers. If a particular service is *"core"* to the business model of the

specialty pharmacy and *"they are already doing it"*, the manufacturer "*should not be paying for it"*. The slide presentation included a list of the typical specialty pharmacy services, which are routinely offered by the PBM Defendants for specialty drug categories, including multiple sclerosis; namely processing/shipping prescriptions, patient benefits verification, refill reminders, customer service numbers, inventory and sales reports, patient adherence calls and patient counseling.

245. Central to this case, Ms. Dunst and Ms. DeLong indicated that virtually all the specialty pharmacy services are patient/unit based and should be valued using the *"Cost Approach"* to FMV determination. This expert commentary is consistent with the Relator's contention that the vast majority of BFSFs for specialty drugs should closely correlate with patient and drug use, unless there is clear evidence of rising service needs or related costs. As such, the Part D BFSFs related to the older Manufacturer Defendants MS drugs should be in significant decline, consistent with their eroding volume and patient use. As such, a massive escalation in BFSFs paid by Manufacturer Defendants to the PBM Defendants tied to service contracts inclusive of severe price increases constitutes rampant FMV fraud. The fee fraud has led to significant overpayment by CMS for the Manufacturer Defendants MS drugs in the Medicare Part D program.

246. Despite the near uniform expert recommendation to use the *"Cost Approach"* in the FMV assessment of the vast majority of BFSFs, conference participants repeatedly admitted that this methodology is not commonly used in practice. A definitive moment in the two-day conference came during the final presentation of the first day given by Jim Abrams, the Director of Government Pricing and Reporting at Mylan Pharmaceuticals. After repeated comments by presenters stressing their legal preference for the *"Cost Approach"* to BFSF FMV assessment, Mr. Abrams took a simple poll of the audience. He asked attendees to raise their hands *"if they were using a rigorous cost plus approach to qualify fees"* at the present time. Consistent with the Relator's investigation, only one person (a consultant) raised his hand, but not a single manufacturer/PBM industry representative in the audience of 40-45 estimated attendees. This feedback confirms that the *"Market Approach"* (almost exclusively using percent of revenue) is nearly universally employed in service arrangements between manufacturers and PBMs and other Service Vendors.

247. In his presentation, John Moose of Huron Consulting also discussed the need for contract adjustments for both increasing drug prices, as well as for changes in service volume (also pertinent to the Manufacturer Defendants' MS drugs which are in declining use). He stated that unless manufacturers put *"adjustments in contracts for price changes"*, they *"run the risk of paying too much"*. He went on state that manufacturers need to *"refresh"* FMV based on a variety of factors, including inflation, changes in service volume, changes in service definition and additional services. However, despite these recommendations and his position at a leading FMV consulting firm, Mr. Moose moments later admitted that to date *"he has not done any refreshes for service contracts"*. This expert commentary clearly indicates that standard *"Percent of*

Revenue" service contracts are rarely being adjusted for price increases, supporting the Relator's allegations of FMV BFSF fraud in the top-spending MS drug category.

248. Additional presentations at the conference also indicated that the lack of cooperation and transparency by large Service Vendors are likely placing manufacturers at considerable fraud risk. The first indication of manufacturer risk came during a presentation by Michael Hepburn (Senior Director of Government Contract Compliance) and Doris Chern (Senior Manager, Pricing Strategy and FMV), both from Johnson & Johnson. First, the JNJ executives reviewed a FMV fee analysis for *"product access services"* that was based upon the *"Market Approach"*, using a *"Requests for Proposal (RFPs) bid process"*, disclosing that the proposals were often *"very hard to compare due to varying services and processes offered by each vendor"*, requiring *"a lot of back and forth with vendors"* to make the offerings comparable. After this process, the executives stated that *"behind the scenes"* they seek to *"assess the cost"* and *"seek reasons from vendors for resources required"*. However, during questioning the JNJ executives admitted that the majority of the *"cost data"* came from the vendors and was not independently verifiable. They admitted that their typical negotiating tactic with vendors after making the RFPs comparable was simply to *"ask for a 10% discount"*. Later, in the final moments of the session, when asked how J&J monitors fees, Mr. Hepburn laughed and said *"that is a good question"*. He then gave general comments about *"internal audits"*, *"validation of services"*, *"education"* and indicated that all *"service agreements go to the J&J Pricing Committee"*.

249. The lack of vendor transparency was further reinforced during the final presentation of the first day by Jim Abrams, the Director of Government Pricing and Reporting at Mylan. After stating that *"customer (i.e., Service Vendors, including PBMs) engagement was very little"*, Mr. Abrams polled the audience of manufacturers and consulting/legal advisors, asking for an indication of who had *"engaged vendors to assess fee structure"*. Out of the 40-45 attendees, only 2 raised their hands. Of these two, one stated that her drug manufacturer employer had *"done a FMV review with vendors"* and *"they were reasonably cooperative"*. The Chairperson of the conference, Tom Evegan of CIS then commented that *"very few vendors were willing to provide the data"* and were *"worried"* about doing so. He expressed concern since *"manufacturers were looking for documentation since manufacturers were responsible if ever challenged"*. Finally, Mr. Shakow of King and Spalding stated that *"up to a few years ago few contracts gave specifics regarding fees"* and this *"could be trouble"*.

250. Greater negotiating leverage in recent years for the Dominant PBM Defendants is supported by direct FMV expert commentary. First, in his previously discussed blog post, Rick Moore, a consultant from CIS (a leading BFSF and FMV consulting firm), indicated that distributor fee rates were on the rise. He stated: *"From our discussions with manufacturers, we are also seeing some significant hardball being played by the Big 3 and other distributors"*. During his conference presentation, John Moose from Huron Consulting said

that he expected the recent favorable trend in contract terms for larger service vendor to *"accelerate"* even further in the future due to their rising negotiating leverage with manufacturers. Feedback from the inaugural FMV BFSF conference clearly indicates that dominant Service Vendors, especially the largest PBM Defendants (Express Scripts and CVS Caremark), achieve highly-favorable *"Percent of Revenue"* service contracts, inclusive of significant price increases, from the majority of drug manufacturers.

251. PBM executives assiduously claim that saving their client's money is their primary objective and that they have had no role in the recent extreme US specialty drug price inflation. For instance, at the start of its Investor Day in November 2012, Mark Thierer, the CEO of Catamaran stated: "*We are a cost containment company servicing payers*". In a January 2013 investor presentation, the former Express Scripts CFO, Jeff Hall, said*: "the sole reason Express Scripts exists is to reduce the cost of healthcare"*. More recently, in public comments discussing the rationale behind the company's *"unprecedented"* exclusion of a small number of specialty drugs from its upcoming 2014 National Formulary for the first time, Express Script's Chief Medical Officer, Steve Miller, stated that *"brand inflation is really problematic for both patients and payers"*, with no mention of any culpability for his organization.

252. In fact, expert commentary from the October FMV BFSF conference indicates that the escalating FMV legal risk faced by drug manufacturers regarding *"Percent of Revenue"* service contracts has actually been primarily driven by the dominant negotiating leverage of large Service Vendors. The first indication at the conference of this power balance came in the final moments of Mr. Shakow's presentation when he stated that the need to shift away from *"percent of revenue"* service contracts was difficult because *"wholesalers and distributors all want percent of revenue deals"* and change required *"getting partners to agree"*. However, the role of service provider leverage was verified more clearly in other comments during event. In his presentation, Mark Dewyngaert, of Huron Consulting, stated that *"often partners (i.e. Service Vendors) will not allow cost plus"* fee determinations. In the second presentation of the first day, the JNJ Assistant General Counsel, Stephanie Gilson, stated that they were *"trying to work with intermediaries"* in order to decrease their reliance on *"percent of WAC" (Wholesaler Acquisition Cost)* contracts, but were getting *"strong pushback from service providers"*. She suggested that to change these business practices may require either a *"manufacturer industry initiative"* or a *"CMS mandate"*. After the review of FMV assessment for specific specialty drug services by Ms. Dunst and Ms. DeLong, Jim Abrams from Mylan commented about the *"practical"* determination of fees in the marketplace. Mr. Abrams stated that, in reality, service contract terms were those *"needed to get or keep the business"* and were determined by the *"business goal of the contract"*.

253. Expert commentary from the October FMV BFSF conference also supports the contention in this complaint that federal government has limited ability/resources to detect Part D fraud at present. The Relator's investigation concluded that CMS is at a significant disadvantage in detecting fraud in Medicare Part D due to

the very limited PBM and manufacturer reporting requirements in the program, particularly regarding BFSFs. First, in a morning session during the first conference day, the long period between the preliminary AMP rule (announced in early 2012) and the still pending final rule was discussed. Ms. Gilson, the General Counsel from J&J, stated that the Office of the Inspector General (OIG*) "has been looking at AMP practices"*, but *"really had little knowledge"* and the *"learning curve takes time"*. She further stated that the OIG auditors had only just *"engaged"* with J&J directly on this issue recently in the *"second quarter of 2013"*. Comments later in the same session were even more telling. Following up from the prior JNJ OIG comments, an attendee agreed that the OIG was *"behind industry"* and asked when the government would be *"dangerous enough to understand how industry works"*. The JNJ Counsel responded that she thought *"CMS was getting burned out because a lot of stakeholders were in their ear"*.

C. Incriminating Biogen Service Contract/Fee Disclosures from Streck Qui Tam 4th Amended Complaint

254. One of the Manufacturer Defendants in this current complaint, Biogen, is also an active defendant in a Qui Tam case related to the handling of discounts and fees in Medicaid, namely *Streck v. Allergan, et al.*, in United States District Court for the Eastern District of Pennsylvania. However, the Streck case has received minimal attention by the general media or investors. In July 2012, the court dismissed the case against *"Service"* defendants in the Streck case, but allowed it to proceed, without government participation, against Biogen and three other *"Discount"* defendants. The Streck case is far different than the allegations outlined in this Qui Tam case. In Streck, the plaintiff alleges that Biogen, and other *"Discount"* defendants, inappropriately accounted for BFSFs as *"discounts"*, leading to lower government AMP *("Average Manufacturer Price")* levels and lower related manufacturer Medicaid rebates to CMS. In Medicaid, decreased recognition of BFSFs (and greater recognition of discounts) may be beneficial to manufacturers since this accounting can lead to lower government prices and lower mandated rebates, especially in the short term. In contrast, in Medicare Part D, manufacturers benefit from increased recognition of BFSFs (and lower recognition of discounts) since this accounting increases government prices, as well as corporate revenues and profits. Importantly, CMS requires that manufacturers account for service fees using consistent methodologies in separate government drug programs, such as Medicaid and Medicare Part D.

255. In the Relator's view, disclosure and discussion in the Streck Qui Tam documents are also highly supportive of the fraudulent manufacturer/PBM Part D BFSF transactions outlined in this complaint, particularly regarding Biogen. As the former head of the Healthcare Distribution Management Association, Mr. Streck had access to *"Distribution Service Agreements" (DSAs)* between manufacturers and major wholesalers, some details of which are disclosed in the Plaintiffs Fourth Amended Complaint filed with the court in September 2011. For all 14 defendants in the case, the wholesalers designated the *"service fees"* (other than perhaps the inventory price adjustments at the center of the Streck case) as *"bona fide"* in nature (i.e., passing the *"Four-Part Test"*, including FMV), thus allowing the fees to be excluded from Medicaid AMP

calculations. The manufacturers concurred with this BFSF designation in almost all instances. However, as will be discussed below, despite wholesalers documenting the *"bona fide"* nature of the majority of service fees in the DSAs, several of the *"Discount Defendants"* in the Streck case, including Biogen, treated the entire amount of *"percent of sales"* based service fees as *"discounts"* in their Medicaid AMP calculations. As per the Pennsylvania court's review, if ongoing, this *"discount"* handling by Biogen appears to be counter to clear BFSF regulations established for Medicaid in 2007.

256. As indicated per Streck Fourth Amended Complaint, 12 of the 14 defendant DSAs, including that for the mutual Defendant Biogen, are structured based upon a *"percent of product sales"*. The other Streck defendants with DSAs based entirely upon a *"percent of product sales"* are Allergan, Bradley, Eisai, Mallinkrodt, Reliant, Sepracor, Upsher Smith, Astra Zeneca, Cephalon and Genzyme. Furthermore, of these 12 Streck defendants with *"percent of product sales"* DSA terms, 9 had specific clauses enabling manufacturers to recover *"value appreciation"* related to subsequent price increases for inventory already on hand at wholesalers, the issue at the center of the Streck case.

257. However, central to this current Qui Tam case, none of the 12 Streck defendants with *"percent of product sales"* DSA terms, including Biogen, had any contract clauses to adjust wholesaler BFSF payments for ongoing drug price inflation (of any magnitude) beyond that for short term inventory valuation adjustments. According to the Streck Fourth Amended Complaint, Biogen and a national wholesaler executed a *"Service Agreement"* ("Biogen SA"), effective April 1, 2005. As per the Biogen Service Agreement (SA), *"Biogen agrees to pay the wholesaler a Service Fee equal to 1% of the volume of all the products purchased"*. While 9 of the 12 Streck defendants with "*percent of product sales*" DSA terms had contract clauses enabling recovery of *"inventory appreciation"* for short term price increases, even this modest price provision appeared to be lacking in the Biogen contract. Furthermore, as with all the other 11 Streck Defendants with *"percent of product sales"* arrangements, the discussion of the Defendant Biogen SA makes no mention of any service fee adjustments for ongoing price increases. The lack of ongoing inflation adjustments in service contracts has only a modest implications for the Streck case since the Medicaid legislation requires the manufacturers to return revenues generated by price increases greater than CPI-U to CMS in the form of additional rebates. However, the implication in Medicare Part D is severe since the program depends upon private market *"negotiated prices"* and has no mandated restrictions on price inflation.

258. Of note, the Group Purchasing Organization (GPO) Safe Harbor to the anti-Kickback Statute explicitly permits GPO administrative fees of up to 3% percent of the purchase price and even more than that amount, if certain steps are taken. Furthermore, the Office of the Inspector General (OIG) of HHS has encouraged manufacturers to base their PBM relationships on this GPO Safe Harbor. *42 CFR 1001.952 (i)* However, a review of a key OIG publication, entitled *"OIG Compliance Program Guidance for*

Pharmaceutical Manufacturers", released on May 3, 2003, indicates considerable fraud concern regarding current manufacturer/PBM arrangements, especially in the US specialty drug markets. *Fed. Reg. Vol. 68, No. 86.* First, the OIG report indicates that current manufacturer/PBM relationships are routinely operating outside the protection of the GPO Safe Harbor which requires that *"payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer."* From the Relator's investigation, it has been determined that escalating BFSFs are the primary path for PBM compensation from manufacturers in the Part D program and that these fees are not typically disclosed to any independent plan sponsors or CMS. Second, even under the GPO Safe Harbor, the OIG requires *that "the remunerations should be fair market value for legitimate, reasonable, and necessary services."* As such, receipt of excessive FMV BFSFs would place the PBM Defendants squarely outside of protection afforded by the GPO Safe Harbor. Of note, the OIG pharmaceutical manufacturer compliance document also includes additional guidance indicating considerable fraud exposure to manufacturers with *"percent of revenue"* service arrangements.

259. The specific contract disclosures in the Streck case regarding Defendant Biogen, are strongly supportive and illustrative of the fraud scheme outlined in this complaint. First, given its signing in April 2005 and the typical multi-year nature of most DSA agreements, the Biogen wholesaler contract was likely in effect for a significant amount of time beyond the January 1, 2006 start of the Medicare Part D program. Second, similar severe US price inflation in both Medicare Part D and the private insurance for Defendant Biogen's MS therapy, Avonex, has been documented by both public databases and Defendant Biogen's own SEC corporate filings. Third, from public databases and Biogen's own SEC filings, significant erosion of US patient usage of Avonex has also been well documented. Fourth, as its long-standing top-selling product, Biogen's Avonex accounted for 62%, 58% and 56% of total US corporate revenues for the years 2005, 2008 and 2012, respectively. Given these facts and terms of the above 2005 service agreement (i.e., percent of revenues and no adjustment for price increases), it is certain that Biogen has paid the *"National Wholesaler"* a considerable increase in *"fees"* directly related to severe US Avonex price inflation in the face of a significant decrease in patient usage. With the *"Cost Approach"* to FMV recommended for virtually all patient/volume-based *"bona fide"* services, Biogen's use of *"Percent of Revenue"* service fee terms, without fee adjustments for massive price increases, is clearly fraudulent.

260. Although the 2005 Biogen *"Service Agreement"* described in the Streck Complaint pertains specifically to a *"National Wholesaler"*, the Relator's investigation indicates that similar *"Percent of Revenue"* manufacturer service contracts predominate regarding the Dominant PBM Defendants and other Service Vendors. In fact, given their dominant role in direct drug benefit management in both Medicare Part D and the private insurance market, PBMs typically obtain far better financial terms than traditional drug wholesalers. This greater negotiating leverage with manufacturers is clearly reflected in the higher profit

margins for PBMs. For example, as per their SEC filings, two leading stand-alone PBMs in the public equity markets, Express Scripts and Catamaran, reported overall profit margins (measured as a percent of revenues) of 5.7% and 3.7%, respectively, for 2012. In contrast, two large US drug wholesalers, Cardinal Health and McKesson, reported far lower operating margins in 2012 of 1.66% and 1.75%, respectively.

261. Another aspect of the Streck case may have important implications regarding Manufacturer Defendant Biogen. On July 3, 2012, Judge Eduardo C. Robreno in the United States District Court for the Easter District of Pennsylvania issued a Memorandum regarding the Streck case. In the court's decision, Judge Robreno dismissed the case against all *"Service Fee Defendants"*, largely due to the ambiguous regulations governing AMP submissions and *"reasonable assumptions"* made by the manufacturers. However, the Judge allowed the case against the four *"Discount Defendants"*, namely Biogen, Genzyme, Cephalon and Astra Zeneca, to proceed for the period after January 1, 2007 when AMP regulations were clarified by CMS. Most of the defendants in the Streck case had handled the vast majority of *"service fees"* as *"bona fide"* in nature (with the exception of *"inventory price appreciation"* adjustments), consistent with the documented terms of the wholesaler agreements. However, Biogen, and two of the other *"Discount Defendants"* (Genzyme and Cephalon), decided to recognize all of the wholesaler service fees as *"discounts"*, leading to lower AMPs and associated government-mandated Medicaid rebates. These three discount defendants made this decision despite contracts that indicate virtually identical services were being provided by wholesalers (i.e., distribution services, inventory management services, data services) as compared to the other Streck defendants. Specifically regarding Biogen, the Fourth Amended Streck Complaint states: *"Despite this, and despite the wholesaler's express position in the agreement that the fees are bona fide for service, Biogen unlawfully elected to rename these fees discounts. Indeed, Biogen expressly states that it will recognize the Service Fees as discounts in its government pricing calculations".* The Relator's investigation indicates that Biogen recognizes fees for similar services as BFSFs for Medicare Part D reimbursement, which though inconsistent and contrary to the classification for Medicaid, maximizes their profitability from Medicare Part D reimbursement.

262. This disclosure suggests a potential pattern of behavior at Biogen that should heighten BFSF fraud concerns in the current case, particularly given the far greater potential magnitude of abuse in Medicare Part D. First, Biogen's handling of all fees as "*discounts"* in the Streck wholesaler contract is clearly outside of industry norms and perhaps counter to clear Medicaid BFSF regulations established in 2007. This unusual and inconsistent classification of payments by Biogen in Medicaid should raise a *"red flag"* regarding the company's handling of service fees in other federal drug programs, especially Medicare Part D. Second, CMS expressly requires that manufacturers handle BFSFs consistently in all government drugs programs, but is aware that financial implications can be quite different in Medicaid compared to Medicare Part D (in large part due to the lack of price inflation limits in Medicare Part D). Consistent with the Streck case, in Medicaid,

decreased recognition of BFSFs (and greater recognition of discounts) may be beneficial to manufacturers since this accounting leads to lower government prices and lower mandated rebates. Since Biogen *"expressly states"* in its above 2005 wholesaler contract that it will recognize the service fees as *"discounts"* in its government pricing calculations, then, by law, it would be required to handle similar fees as *"discounts"* in contracts with the PBM Defendants in Medicare Part D. However, the Relator's investigation has already revealed that the vast majority of PBM compensation in Medicare Part D has been via BFSF payments from manufacturers that are excluded from *"negotiated price"* calculations and largely unreported to CMS. The ongoing massive inflation of the cost of Biogen's Avonex in Medicare Part D verifies that manufacturer discounts have been a minor part of PBM compensation in the program. This indicates that Biogen appears to be using contrary, and therefore unlawful, accounting methodologies for BFSFs in different government drug programs.

263. In this complaint, the Relator repeatedly uses the term "*Market Approach/Percent of Revenue"* to describe the nature of manufacturer/PBM service contracts in the Medicare Part D program. The Relator uses this hybrid phrase for a specific reason, even though his extensive investigation has determined that straightforward *"percent of revenue"* arrangements, "*without fee adjustments for price increases",* are employed in the vast majority of manufacturer/PBM service contracts. *"Percent of revenue"* service contracts, as practiced in the marketplace, are a type of *"Market Approach"* FMV fee assessment. In the *"Market Approach"* to FMV analysis, the valuation is determined by a comparison to prevailing prices in the marketplace. As such, in Medicare Part D, a manufacturer may decide to determine the FMV of a service contract with a PBM based upon the financial terms of competitor relationships. This approach carries significant fraud risk under the Anti-Kickback Statute if the market is *"anti-competitive"*, as is alleged for the US MS market in this complaint. However, the Relator also discovered in his investigation that some manufacturers have become more sophisticated in their service contract arrangements and are not using straight *"percent of revenue"* arrangements, perhaps due to concern regarding increased government scrutiny or due to the increased practice of using outside consultants for the assessment of BFSFs and FMV. The potential for increased complexity in PBM service contract arrangements is evident from the previously mentioned quote at the October 2013 FMV BFSF conference from Julie DeLong, the head of the FMV/BFSF practice at Navigant Consulting, a leading advisor to drug manufacturers. These comments are worth repeating. Ms. DeLong stated that she *"can value anything"* and was comfortable *"translating per unit fees to percentage of revenue"*. Ms. DeLong further indicated her flexibility in the handling of fees between manufacturers and specialty pharmacy service providers. She stated that *"some want to be paid in different ways"* and that she could *"translate FMV into a dollar amount per month or year, as well as a percent of revenues"*.

264. Ms. DeLong's candid comments clearly indicate that she has been involved in manufacturer service contracts that have been structured to provide fees to vendors commensurate with *"percent of sales"* arrangement, but by alternative mechanisms. While Ms. DeLong's *"flexibility"* can be employed in legitimate FMV fee determinations, it also suggests increased complexity and potential fraud risks, especially for drugs with severe price inflation as has occurred with the Manufacturer Defendants' MS drugs. For instance, a justification of increased *"per unit"* fees for the massively inflating Defendants' MS drugs in recent years would require either a sharp increase in the valuation of existing PBM/specialty pharmacy services or significant new services, neither of which is evident from the Relator's investigation. With alternative fee arrangements, discovery efforts will need to be highly diligent and look beyond the basic terms of complex service agreements to assess for bogus fees, redundant services, or extreme changes in the valuation of itemized, individual services. While the Streck case documents indicate that Biogen employed a straightforward *"percent of revenue"* fee contract (without price adjustments) with a national wholesaler, the manufacturer's fee arrangements with other service vendors may be far different. However, regardless of actual service contract terms, the glaring *"red flag"* in the investigation of all the Defendants should be evidence of significantly escalating BFSFs, despite documented proof of stagnating or declining patient usage/prescriptions for the Manufacturer Defendants MS drugs.

265. The potential for increased service fee contract complexity is evident from a review of disclosures in the Streck Fourth Amended Complaint. As mentioned previously, 12 of the 14 Streck defendants used *"Percent of Revenue"* terms in their wholesaler contracts. However, two Streck defendants, Amgen and Novo Nordisk, employed far different contract terms despite very similar, largely standardized, services being provided by the wholesaler partner. As per the Streck Complaint: Section 1 of Amgen's WDA ("Wholesaler Distribution Agreement") *"describes the "Order Fulfillment Service Fee" whereby Amgen pays a fee to the wholesaler of up to $1,189,200 based on the wholesaler's order fulfillment rate. Section 2 details information services that the wholesaler provides in exchange for monthly "Data Fees" of up to $261,076. Section 3 details an "inventory management performance fee" of up to $396,400".* Also from the Streck Complaint: *"For 2006, Novo Nordisk agreed to pay a quarterly fee equal to $1.25 million, multiplied by "1 plus the percentage change in the CPI index between 2005 and 2006..., subject to a minimum multiplier adjustment of 1.025. Novo Nordisk would also adjust the wholesaler's fee to reflect the percentage increase or decrease in product sales by the wholesaler between 2005 and 2006."* Despite the different structure of the Amgen and Novo Nordisk wholesaler contracts, the manufacturers are also legally required to justify to CMS the FMV of services provided by the wholesaler based upon the *"Four-Part Test".* The structure of these contracts reinforces the need for increased diligence in assessing potential fraud as complexity increases.

HISTORICAL BACKGROUND OF THE PBM INDUSTRY

266. Pharmacy Benefit Managers (PBMs) are organizations hired to manage both the delivery and cost of drugs for a wide array of third parties, including large and small employers, HMOs, unions and government entities. Although it originated a decade or so prior, the PBM industry's influence greatly escalated in the late 1980's during boom times for traditional pharmaceuticals, when the leading US companies sold predominantly *"pills"* via massive primary care sales forces. During those times, drug costs were skyrocketing because payers had limited ability to offset this massive marketing muscle at a time when pipeline output from the industry was relatively strong, generic alternatives were limited and large prices increases were routine.

267. Into this milieu, the nascent PBM industry offered large corporations and HMOs cost management techniques for the first time. The PBM industry recognized that due to limited payer pushback, the pharmaceutical industry had created a considerable amount of redundancy in its product offerings. Because the industry believed it could sell virtually any product with enough sales representatives, they developed many low development risk, branded, *"me-too"* products in major therapeutic categories such as cholesterol-lowering, hypertension and depression. As its client base grew, Medco, the dominant PBM of the early years, proceeded to extract increasing price discounts from major pharmaceutical companies seeking market share in crowded branded therapeutic categories *("therapeutic substitution"*), while also increasing the use of generics *("generic substitution")*. In this ruthless business, drug manufacturers that provided greater branded discounts were included on Medco's preferred *"formularies"*, while others were largely shut out of its client base. In particular, Medco used its unique, high-efficiency, mail order pharmacy capabilities with great success to shift market share towards its preferred branded drugs in the marketplace. Over time, numerous other PBMs arose to serve this booming market, hastening the transition.

268. PBM profits historically came from two primary sources; prescription transaction fees, as well as discounts and/or rebates extracted from drug manufacturers. In the ensuing decades, the PBM industry and its clients also benefited greatly from patent expirations for many of the major drugs of the earlier era. Although perhaps counterintuitive to many outside of the healthcare space, PBMs typically make more money on lower-priced oral generics compared to branded pills due to greater pricing flexibility and lower acquisition costs. Most importantly, the PBM industry provided considerable financial benefits to its clients and beneficiaries through lower drug costs and other services, such as compliance and education programs. It is also important to note that in these early years, high-priced specialty drugs represented a very small part of both US drug spending and PBM efforts.

269. If one fast forwards to the present day, the dynamics of both the pharmaceutical and PBM industries have change dramatically. With many of the blockbuster oral drugs of the past few decades now

generic, the PBM industry has already tapped most of the profit potential from this highly profitable conversion. While about 55% of US oral prescriptions were low-cost generic drugs as recently as 2006, the generic penetration now approaches 80%; future gains and associated PBM profits will likely only be incremental. See **Exhibit 41**. In addition, with more than 90% of health plans now offering mail order service and recent PBM industry data suggesting rising price competition from retail networks, profit opportunities in this mainstay cost-savings strategy is also diminishing. In fact, according to the data company IMS, the mail order share of the overall US prescription market has actually been declining over the past 3 years. See **Exhibit 42**.

270. Within the pharmaceutical industry, changes have been just as seismic in recent years. With many safe and effective generic products now available across all the major primary care target markets (cholesterol, hypertension, neurologic therapies, antiulcerants, antihistamines, insomnia, oral antibiotics), traditional drug pipeline output in these therapeutic areas ground to a near standstill. After a period of massive consolidation and cost-cutting, the pharmaceutical companies have increasingly adopted the technologies and business strategies of the burgeoning biotechnology industry, namely developing specialty drugs for severe medical conditions (e.g., cancer, autoimmune diseases, rare genetic disorders) that can achieve high pricing and profits with far less marketing cost. As all healthcare investors are acutely aware, almost all of the top-performing stocks in the sector in recent years have been biopharmaceutical companies following this strategy. With the opportunity from generic and mail order programs diminishing, the PBM and related distribution businesses have also aggressively pursued the opportunity to manage the use of these specialty drugs for their clients, providing a much-needed new, high-growth revenue stream.

271. Recent public commentary from major PBM executives verifies origins of the industry and the shift towards specialty drugs in recent years. At its sixth annual Investor Day held on November 15, 2012, Dr. Sumit Dutta, the Chief Medical officer of the PBM Catamaran (and a former executive at Medco, the first leading PBM) started his presentation by discussing the early days of the PBM industry: *"When I first started in the industry, the profit drivers in the PBM industry were rebates on branded manufacturer products. ...and then we saw after that was a wave of profitability from generics....pharmaceutical companies focused on delivering new drugs, me-too drugs, and setting price. And the counterparty to that, or the PBMs, who negotiated rebates, price, created clinical programs to eliminate inappropriate utilization"*. The former Chief Financial Officer of Express Scripts, Jeff Hall, made similar comments at a leading investor conference on January 8, 2013: *"In the early days, our primary tools were retail networks and rebates. We evolved that with innovative tools to drive generics to low-cost brands. We created world-class clinical offerings. More recently, we've developed tools to increase the use of home delivery, improve the cost and quality of specialty drugs"*. In the same presentation Mr. Hall provided a slide indicating that specialty drug spending for Express Scripts clients has grown on average 20% each and every year since 2005. Despite going on to state that specialty

drugs are *"one of the top concerns of almost every client we talk to today"*, Mr. Hall, forecasted little change for the future; *"we are seeing 20% plus trend going forward"*.

LONG-ESTABLISHED *"THERAPEUTIC SUBSITUTION"* CAPABILITIES OF PBM DEFENDANTS

272. As a veteran Wall Street healthcare analyst who has followed the PBM industry closely since its inception, the Relator has first-hand knowledge that *"therapeutic substitution"* was the basis for its founding. Two long-standing PBMs executives admitted the same in quotes above. One of the best examples of PBM capabilities comes by examining the role that Medco (the first large PBM) played in the early 1990s in the intense battle for market share among branded cardiovascular drugs at Merck and other major pharmaceutical companies. At the time, Merck sold the leading branded cholesterol drugs, Mevacor and Zocor that competed intensely with Bristol's Pravachol. In the hypertension market, the competition was even fiercer between Merck's ACE (Angiotensin Converting Enzyme) inhibitor franchise (Vasotec and Prinivil) and products from Bristol Myers, ICI, Ciba and Warner Lambert. Much like the current MS dynamics, the products in these cardiovascular therapeutic areas were quite similar in profile, with modest efficacy and safety differences. As a large brokerage firm pharmaceutical equity analyst at the time, the Relator tracked these important trends on a weekly basis in the early 1990's using IMS prescription data. Between November of 1992 and November of 1993, with its product blocked out of most Medco formularies, Merck faced severe competitive pressures in the cardiovascular markets. In the ACE inhibitor market, in just 12 months, Merck's overall market share fell 4.6% points, from 49.0% to 44.4%. With somewhat less competition, Merck's share of the cholesterol market fell 1.7% in the year ending November 1993, from 49.3% to 47.6%. See **Exhibit 43**.

273. However, the greatest validation of *"therapeutic substitution"* programs and the impact of the PBM industry came in November 1993 when Merck consummated its controversial acquisition of Medco. Not surprisingly, after the merger, Merck quickly reversed its deterioration in the major cardiovascular categories, regaining 1.5% and 1.0% of share in the ACE inhibitor and cholesterol markets, respectively, just 3-4 months after closure of the merger. See **Exhibit 43.** With preferred positions in Medco retail and mail order networks, Merck went on to aggressively defend its core franchises for years to come. Facing similar threats to core branded therapeutic areas, Eli Lilly and SmithKline Beecham went on to acquire the two other major PBMs of the time, PCS Health Systems and Diversified Pharmaceutical Services (DPS), in 1995.

274. In the Relator's estimation, if PBMs were currently acting in the best interest of their clients, the savings opportunity regarding the Manufacturer Defendants' MS therapies would be substantial. First, in the early 1990's, Medco had a dramatic impact on the largest drug companies in the world when the PBM industry was a fraction of its current size. For reference, Medco generated revenues of approximately $3.0 billion in

1993, accounting for only about 5% of the $60 billion US pharmaceutical market at the time. In comparison, after massive growth and consolidation, for 2013, Express Scripts and CVS Caremark, the two largest PBMs, are expected to have revenues in the $95 billion and $75 billion range, respectively. See **Exhibit 30.** These two companies alone now account for about 50% of the overall US pharmaceutical market (and about 65% of Part D plans), with the entire PBM industry now managing about 82% of drug spending in the country. Normal competitive dynamics would suggest that PBM negotiating leverage should be far greater and more sophisticated at the present time compared to 20 years ago. Second, Merck was a large diversified company in 1993, suggesting it had considerable leverage in contract discussions as PBM sought to maintain access to other more *"unique"* drugs in Merck's portfolio. In contrast, the MS drugs at Biogen and Teva account for more than half of company profits, which should greatly escalate PBM leverage in such a crowded therapeutic category. Third, Medco had considerable success getting discounts and moving market share in the early 1990s in cardiovascular segments with very strong volume growth at the time (14% year over year for ACE inhibitors and 28% year over year for HMG Co-A cholesterol agents in November 1993); the battle for market share in the stagnant MS market, with only 0-2% annual prescription growth in recent years, should be even fiercer. Finally, PBM cost savings tactics should be easier to apply to the smaller MS physician and patient target segments compared the vast cardiovascular primary care markets. In a normal competitive environment, the motivation to switch a single $40-50,000/year MS patient to another drug with even a modestly lower price should be extreme. In contrast, shifting share in the cardiovascular space in the early 1990s required a vast program to alter the behavior of many primary care doctors. With all these factors, there is little doubt that price competition among the Manufacturer Defendants' MS agents would be severe if PBM interests were truly aligned with their clients.

MANUFACTURER & PBM INDUSTRY SHIFT TO *"SPECIALTY DRUGS"* CENTRAL TO FRAUD

275. Due to a wide array of major patent expirations and subsequent price erosion, overall US spending on traditional *"pills"* has moderated considerably in recent years, with sales growth of only 0-1% in 2010 and 2011, with trends actually turning negative for the first time in 2012 according data recently released by the PBM, Express Scripts. See **Exhibit 41**. In its most recent Drug Trends Report, Express Scripts reported a 2.4% traditional market increase in the commercial insurance segment in 2013 and no year-over-year growth in Medicare market. In recent years, the PBM industry has very efficiently managed an increase in generic penetration in the traditional market from 56% in 2006 to nearly 80% at the present time, generating significant client savings in the process.

276. However, the more sinister part of this generic conversion has been the *"cover"* that the traditional drug market spending slowdown has provided to the PBM Defendants as they seek to greatly benefit from the

burgeoning profits available to them in recent years in their murky handling of specialty drugs, often to the detriment of their own typically less-sophisticated clients. With the traditional drug market spending slowdown, even with 15-20% specialty drug annual growth, many PBM clients claim satisfaction with modest overall drug spending growth in the 3-5% range in recent years, unaware that significant potential specialty drug savings remain unrealized. Unfortunately, with fewer traditional patent expirations and a forecast for continued strong specialty drug spending, overall US drug spending is expected to re-accelerate in the future. In fact, according to the 2013 Medicare Trustee report, average annual Medicare Part D spending is forecasted to rise 9.5% annually between 2013 and 2022, largely driven by high-priced specialty drugs. Forecasted Medicare Part D spending trends are discussed in greater detail later in the complaint.

277. In recent years, the slowdown in traditional drug market spending has increased the growth dependence of both the biopharmaceutical and PBM industries on high-priced specialty drugs, including the large multiple sclerosis category. With these disparate growth trends, specialty drugs accounted for nearly 50% of overall US pharmaceutical growth between 2004 and 2011, despite accounting for only 18-25% of market share during the period. With similar future trends forecasted by the PBM industry and other market participants, specialty drugs are expected to account for 75% of US drug spending growth over the next several years. See **Exhibit 44.**

278. The transition from *"traditional drugs"* to *"specialty drugs"* has caused a sharp shift in business models for both the drug manufacturer and PBM industries. Several decades ago, the PBM industry originated and prospered by pursuing savings for its health plan clients via discounts for *"preferred"* products in crowded branded categories (i.e., *"therapeutic substitution"*). However, more recently, with limited *"traditional"* opportunities due to high generic and mail order penetration, PBMs have received escalating compensation by *"cooperating"* with manufacturers in passing severe price increases (particularly for high-cost specialty drugs) on to less-sophisticated clients, including CMS and elderly beneficiaries in Medicare Part D.

279. However, the most startling aspect of the US specialty drug market in recent years has been the little-discussed role that severe price increases have played, especially since the 2006 start of Medicare Part D. In fact, the meteoric growth in US specialty drug spending in recent years has actually been fueled primarily by massive price increases on many older drugs, rather than a wealth of innovative new drug launches as industry participants often claim. Data from the PBM industry itself clearly supports these market dynamics. **Exhibit 45** provides the components of US specialty drug growth from the annual Drug Trend Reports released by Express Scripts, the leading US PBM. For each year between 2008 and 2013, price increases on existing specialty drugs accounted for 56-102% of spending growth in Express Script's client base. In contrast, new drug introductions accounted for less than 10% of overall specialty drug growth each year, with the

exception of 2011. Of note, Express Scripts stopped disclosing the specific contribution of new drugs to growth in starting in 2012.

280. Within Express Script's Medicare segment, the contribution of drug cost has been even more extreme, with pricing accounting for 58-111% growth each year from 2010 through 2013. Despite years of massive price inflation, the recent Express Scripts data regarding specialty drugs in the Medicare segment is even more troubling. For 2012, Express Scripts reported a 24% increase in specialty drug spending in its Medicare client base, with a 26.8% contribution from drug cost and a -2.7% decline in utilization. In its most recent Drug Trends Report for 2013, Express Scripts reported a decline in specialty drug utilization in Medicare for the second year in a row (down -0.6% year-over-years vs. 2012), with a 14.7% growth in spending fueled entirely by cost increases. See **Exhibit 46**.

281. While extreme price increases have been a driving force in numerous US specialty drug areas, the inflation has been among the most severe in the large MS category, dominated by the Manufacturer Defendants' long-marketed MS therapies. According to the Express Scripts Drug Trends Reports, price increases on existing drugs accounted for 57-128% of US revenue growth in the MS category each year from 2007 through 2013. With the four leading Manufacturer Defendants MS drugs (Avonex, Copaxone, Refib and Betaseron) accounting for 100% of US category sales in 2005 and still 79% in 2012, their massive nearly five-fold price inflation has been the driving force in the category. Despite declining volume for the Manufacturer Defendants MS drugs, US commercial market spending in the category has increased by 16-33% each year from 2007 to 2013, according to the Express Scripts Drug Trend Reports. See **Exhibit 47**.

282. The MS spending trends in the Medicare population have been quite similar. According to Express Scripts, Medicare MS spending grew by 21%, 34%, 27% and 20% in 2010, 2011, 2012 and 2013, respectively, primarily driven by massive price inflation. See **Exhibit 46**. According to Express Scripts data, price increases accounted for 41-71% of the Medicare annual MS growth over this time range. However, as discussed earlier in the complaint, the Relator suspects that Express Scripts is under-reporting the impact of well-documented massive MS drug US price increases in recent years.

283. Furthermore, nearly identical growth/pricing trends for the overall specialty drug market and the multiple sclerosis category has been documented at other PBMs and from other public databases. For instance, the PBM SXC Health Solutions (now part of the public PBM, Catamaran) reported a 21.3% annual increase in MS drug spending within its client base in its 2011 Informed Trends report, with price increases accounting for 78% of the growth. Within its client base, SXC Health reported US price increases of 12.0%, 15.7% and 22.4%, for Biogen's Avonex, EMD Serono/Pfizer's Rebif and Teva's Copaxone, respectively, for 2011 alone.

284. The Relator believes a review of recent US versus international trends for Biogen's Avonex, as reported in the company's Securities and Exchange Commission (SEC) 10K filings, also indicates domestic anticompetitive behavior. Of note, Biogen is the only company among the Manufacturer Defendants that has disclosed price and volume data for its MS therapy. Overall, Biogen reported a robust 41% increase in US Avonex sales, from $1.277 billion in 2008 to $1.794 in 2012, despite also disclosing that US Avonex patient volume had declined by approximately 25% during the four years. According to the 10K reports to the SEC, Biogen's US Avonex sales growth benefited from a 12-24% price increase contribution each year from 2008 through 2012. See **Exhibit 48**. The unusual dynamics of US Avonex trends are in sharp contrast to the product's performance in international markets during the same time period. Despite a reported 26% increase in volume over the 4 years, Avonex international sales growth was half of that in the US market over the period. Despite strong international volume trends, pricing reduced international Avonex revenue growth in three of the five years from 2008 to 2012.

285. This Qui Tam case targets alleged Medicare Part D BFSF fraud and related price collusion in the US multiple sclerosis market. However, the Relator sees significant signs of anticompetitive behavior in other specialty drug therapeutic categories, including treatments for pulmonary hypertension, infectious diseases, rheumatoid arthritis, diabetes and cancer. For instance, the treatment of Chronic Myeloid Leukemia (CML), a cancer that affects approximately 4,500 Americans each year, has been a hotbed of industry research since the launch of the innovative first targeted oral treatment, Novartis' Gleevec in 2001. Since then, four other similar CML therapies have been launched; Bristol Myer's Sprycel (2006), Novartis' second entry, Tasigna (2007), as well as more recent products from Pfizer (Bosulif, September, 2012) and Ariad Pharmaceuticals (Iclusig, December, 2012). Despite declining market share and a saturated market, the annual US cost per patient for Novartis' Gleevec has nearly tripled from about $29,000/patient in mid-2005 to nearly $77,000/patient at the present time. See **Exhibit 49**. The annual cost for Bristol Myers' Sprycel has risen from about $60,000/patient/year in 2008 to about $103,000 currently. Similar to the pattern in the MS and other specialty markets, the ever increasing pricing plateaus in the CML space counter-intuitively seem to provide even greater flexibility for newer products. In September 2012, Pfizer's Bosulif was launched at an annual cost of about $98,000/patient, while Ariad's Iclusig became available at $115,000/patient in December 2012. Based upon pricing levels from public databases and US sales reported by Novartis, it is estimated that US-treated Gleevec patients grew about 20% between 2006 and 2009, but volume been stagnant to down since then due to market share losses to newer agents. However, due to unabated extreme price increases, US sales growth has remained strong, rising from $1.09 million in 2009 to $1.7 billion in 2012, entirely due to price inflation.

286. Furthermore, similar to the situation with MS drugs, the US cost of CML therapies are now 2-3 times the level for the same products in many international markets. See **Exhibit 50** for a geographic cost comparison of leading CML therapies from another leading database. As such, regardless of the greater

complexity in treating cancer patients, normal competitive dynamics do not appear to be operating as new CML drugs are added to an already mature US marketplace. Of note, the potential for Part D BFSF fraud related to these CML therapies could be considerable because as oral therapies (unlike most cancer therapies, which are injectable), the vast majority of the CML drug category is administered through the pharmacy benefit.

ADDITIONAL BACKGROUND ON SPECIALTY DRUG AND PBM COMPETITIVE DYNAMICS

287. The rising dependence of PBMs on specialty drugs for both revenue growth and profitability has also been well-documented from the public disclosures of several leading public companies, namely Express Scripts, CVS Caremark and Catamaran. In 2011, Express Scripts, the largest public PBM, reported Specialty Drug Segment sales of $14.6 billion, up 8.6% versus the prior year, which accounted for 33% of the company's revenues for the year and all of its overall corporate growth. See **Exhibit 51**. In fact, Express Scripts reported traditional drugs sales of $30.0 billion in 2011, which actually declined 0.5% year over year. As with all PBMs, virtually all Express Scripts revenues are in the United States. Although not separately reported, with far higher margins, specialty drugs very likely accounted for an even greater portion of Express Scripts 11% operating profit growth in 2011. Of note, in 2012 Express Scripts merged with the country's second largest PBM, Medco; in September 2012, the merged company reported quarterly specialty drug sales of $9.6 billion, representing an even higher 37% of a much larger entity. During its December 2012 Investor Day, CVS Caremark provided for the first time some details regarding its specialty drug business segment. In a slide from the presentation, management disclosed that its specialty drug sales rose from $10.9 billion in 2010 to $12.3 billion in 2011, followed by a 48% leap to $18.3 billion in 2012. In 2012, specialty drugs accounted for 37% of CVS Caremark's overall revenue growth vs. only 12% of growth the prior year.

288. The dominant role of specialty drugs for PBM growth is clearly indicated by a quote from the specialty drug section of the Catamaran website: *"With generic alternatives mitigating the cost of traditional medications, specialty medications now account for virtually all the growth in the US drug spend. In fact, specialty medications are projected to surpass spending on traditional medications by 2018 (in Catamaran's client base), climbing from 2012's $290 per member per year to $845."* - representing a nearly 200% increase over the period. Both Catamaran and CVS Caremark highlighted the rising dependence on specialty drugs in recent investor disclosures. On November 20 2013, CVS Caremark released a report entitled *"Insights 2013 - Specialty Trend Management: Where to Go Next"*, in which the company forecasted a tripling of US specialty drug spending to more than $400 million by 2020. On the same day, Catamaran held its Annual Investor Day where management forecasted that specialty drugs to account for 43% of overall drug spending by 2020, up from about 22% at present.

289. Another central tenet of the PBM industry is its broad lack of transparency. Understandably PBMs do not typically share the terms of individual corporate and health insurer client contracts with other constituents for competitive reasons. However, there is also a tremendous amount of variability regarding the financial terms and transparency available to individual PBM clients, with large employers typically having far greater negotiating leverage**.** Fortunately, one of the PBM industry's leading trade organizations, the Pharmacy Benefit Management Institute (PBMI), provided valuable insights on this issue in a recent report released in 2013. For its 2012-*13 "Prescription Drug Benefit and Plan Design Report"*, PBMI surveyed 424 US health plans regarding drug negotiating metrics, providing insights regarding capability by employer size for the first time. First, the report states that 25% of clients do not receive any rebates from their PBM, including 11% of large employers (>5,000 employees) and 34% of small employers (<5,000 employees). See **Exhibit 52**. Second, among those that do receive PBM rebates, large employers receive up to 2.5 times the amount of small ones. Third, smaller clients also have less resources; the same PBM-industry sponsored survey admits that *"only the largest employers dedicate a full-time Human Resources employee to managing the drug benefit"*.

290. Already limited transparency is far greater in the PBM management of specialty drugs. The same PBMI report indicates that only 19% of employers and 33% of health plans self-report a *"high"* understanding of the specialty drug market. See **Exhibit 53**. However, more than 60% of PBM clients in the same survey indicated that decreasing costs was a key focus in managing specialty drugs, while 70-88% of plans also expressed a strong interest in further education regarding specialty drugs. See **Exhibit 54**.

291. Two key findings should be clear from the PBM industry's own data, previously discussed. First, specialty drugs are the primary growth opportunity for the PBM industry going forward. Second, virtually all clients indicate that specialty drug education and cost control are their greatest current needs. With these two factors, in an efficient market place, one would think that PBMs would be fiercely competing to differentiate their specialty drug offerings to clients. Unfortunately recent evidence suggests otherwise. On January, 13, 2013, a major investment firm held a conference call with David Dross, the National Leader of the Managed Pharmacy Practice for Mercer, a leading health consultant firm that advises major corporations and health plans. Regarding PBMs, the Goldman analyst concluded from the discussion: *"There is little differentiation among Specialty offerings, as lack of therapeutic alternatives result in few formulary choices"*. *Goldman Sachs research note, 9/25/13.* As previously indicated, this broad generalization regarding specialty drugs greatly misrepresents the *"therapeutic substitution"* opportunities in crowded therapeutic categories, such as multiple sclerosis, rheumatoid arthritis and some segments of oncology.

292. According to a January 2013 survey performed by Leerink Swann, a major healthcare investment firm, less than 5% of the health plans identified specialty drug capabilities as a key driver in its selection of a

PBM. *Leerink Swann analyst report; PBM Survey Highlights of Key Trends, 1/22/13*. This same survey of 38 health plans indicated less than a 1% increase in client discounts between 2012 and 2013, indicating minimal price competition among PBMs. With little difference among PBM offerings, there is little incentive for clients to endure the disruption and cost of changing PBMs for its health plans. As such, 94-97% of clients retain the same PBM when their multi-year contracts expire in any given year.

293. The PBM industry cites these retention statistics as an indication of its strong performance and client satisfaction. In reality, the lack of client movement is the indicative of the pervasive lack of price competition among rapidly-inflating specialty drug offerings. Given the current collusive dynamics, as long as the costs of specialty drugs rise at a similar pace throughout the PBM industry (as has been occurring), there is little reason for client's to withstand the dislocation of switching PBMs. On a positive note, the survey above also hinted at a tremendous opportunity for PBM competition and cost savings in the future. In the survey, among 7 plans that were currently managing their drug costs on their own, 4 said they would consider hiring an outside PBM offering only a 5% cost savings benefit. Given the meteoric recent price increases for many older specialty drugs, especially the Manufacturer Defendants MS therapies (with price increases averaging 10-25% per year), this level of modest savings would be quite easy to achieve for clients in a truly competitive PBM marketplace.

294. Given the lack of specialty drug service competition, it should come as no surprise that a closer look at the specialty drug service offerings of leading PBMs suggests minimal differences among the group. See **Exhibit 55**. As per their specialty pharmacy websites, all three PBMs, Express Scripts, CVS Caremark and Catamaran, provide nearly identical services across all specialty drug therapeutic areas, including the multiple sclerosis category. Key services provided by all three PBMs for specialty drugs include express shipping, education/instruction, injection training, 24/7 on call phone support, assistance with prior authorization and convenient ordering. Furthermore, since these leading PBMs appear to offer relatively little service directly to manufacturers, the associated fairly-valued compensation should be modest, especially for the Manufacturer Defendants' MS drugs, due to their declining use.

ADDITIONAL MEDICARE PART D RELEVANT FACTORS

295. The catalytic event for severe anticompetitive US specialty drug price inflation in the multiple sclerosis therapeutic category was the passage of the Medicare Part D outpatient drug program in 2003 and its enactment in January 2006. Before Medicare Part D, high drug costs placed an extreme financial burden on many elderly Americans, especially those needing access to high-priced specialty drugs. While Medicare Part D has provided tremendous benefit to seniors, the Relator's investigation has determined that the *"flexible"*

nature of the legislation regarding industry practices and its limited oversight has opened up the floodgates for collusive price inflation, especially regarding specialty drugs which have increasingly become the key revenue/profit driver for both manufacturers and PBMs.

296. The Relator's investigation concluded that the industry-favorable nature of the Part D legislation has apparently limited CMS's ability to detect fraud, especially regarding high-priced specialty drugs. According to the Part D legislation, CMS requires two key reports to be filed with the government on a regular basis. First, Part D sponsors are required to file an annual *Direct and Indirect Remuneration Report (DIR)* in which *"aggregate values of the types of price concessions each plan receive from any source, such as those received from pharmacies or rebates from drug manufacturers". GAO Report, GAO-08-1074R, 10/30/08*. Because plan sponsor DIR reports are used to calculate payments (reconciliation and future premium rates), they are subject to audit and sponsors must attest to their accuracy. However, because these DIR reports contain only *"aggregate"* data at the plan level, CMS claims they are of limited value in detecting potential drug pricing fraud within Medicare Part D. As indicated in the GAO report released on October 30, 2008, the comparison of data across similar plans may help "*identify outliers*". For example, *"among plans with similar characteristics, officials compared plans' reported DIR data in relation to their total drug spending to determine whether any reported DIR seemed particularly high or low….where they found inconsistencies, officials contacted the sponsors to determine whether the inconsistencies could be reasonably explained." GAO Report, GAO-08-1074R, 10/30/08.*Without any specific data regarding individual manufacturers, individual drugs or specific therapeutic categories, plan sponsor DIR reports offer little potential to identify specific cases of pricing fraud within Medicare Part D. Furthermore, this high-level data would fail to identify broad-based pricing fraud in a specific specialty drug areas, such as multiple sclerosis, because prices have been rising sharply and uniformly for virtually all Part D plans (i.e., no *"outliers"*).

297. CMS also requires Part D sponsors to file quarterly price concession reports which include some of the same DIR information, but with some differences. These quarterly reports also include price concessions by individual drug (as opposed to aggregate data in the DIR), such as rebates, other discounts and coupons. Since the quarterly reports are not used to determine program payments, CMS does not subject this data to financial audit. Unfortunately, CMS officials indicated that "*comparison of the DIR data with the quarterly manufacturer price concession data provided only a high-level check for reporting inconsistency because the two sets of data did not capture the same information." GAO Report, GAO-08-1074R, 10/30/08.*

298. Regardless of DIR and quarterly price report limitations, CMS receives real time evidence of the massive price increases for the Manufacturer Defendants MS drugs in Part D via the "*Prescription Drug Event"* (PDE) records filed with each and every Part D prescription. However, thus far the Relator has found no public indication from CMS of significant concern regarding the severe price inflation.

299. As in the private sector, in Part D program the effective use of drug formularies is considered essential for effective cost management. The guidelines for formulary management within the Part D program are provided in Chapter 6 of the *Medicare Prescription Drug Manual*. Unfortunately, it is hard to imagine that these guidelines could be more favorable to industry, especially regarding the handling of specialty drugs. First, regarding the formulary Pharmacy and Therapeutics (P&T) Committee, which is primarily responsible for drug inclusion decisions based on clinical criteria, CMS only requires that it contain one practicing pharmacist and one practicing physician who are *"independent and free of conflict with respect to the Part D sponsor and pharmaceutical manufacturers."* Even for these two committee members, CMS states that they *"may have certain non-employee relationships with pharmaceutical manufacturers (for example consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence."* Furthermore, the regulation pertains only to conflicts with manufacturers, with no guidance regarding financial interests with other entities involved in implementing the Part D program, such as PBMs. With typical P&T committees having 10-15 members, these minimal requirements assure that virtually all formulary drug selection decisions are controlled by PBMs within the Part D program.

300. Second, while CMS requires that each P&T committee member sign an undefined *"conflict of interest"* statement, the policing of this issue has been minimal to date. In fact, in a recent March 2013 HHS OIG report, CMS admitted this glaring deficiency, stating, *"CMS staff reported that they do not look at the information that sponsors and PBMs report about whether each P&T committee member is free of conflict. Without reviewing this information, CMS cannot know whether a minimum of two members on each P&T committee are free of conflict with sponsors and pharmaceutical manufacturers, as required." OIG report OEI-05-10-00450, Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions, March 2013, p 16.*

301. Third, the Part D legislation allows confidential agreements between PBMs and Part D sponsors, such that the latter is not informed of the membership composition of its P&T committee. CMS does require that sponsors *"ensure"* that the PBM submits this P&T committee data directly to the government. By allowing independent plan sponsors to be blocked from this important formulary information, CMS has diminished the potential for fraud detection in the program. Unfortunately, in practice, this exclusion has little impact because Part D is dominated by the fully-integrated PBM Defendants.

302. The unique handling of specialty drugs in the Part D formulary guidelines appears to provide the drug manufacturers and PBMs with the cover to avoid cost management and has helped enable massive price

inflation. According to statue *42 CFR 423.578(a)(7)* of the Part D legislation, Part D sponsors are allowed to *"exempt"* from *"tiered cost-sharing exceptions"* a *"formulary tier, in which it places very high cost and unique items"*. Furthermore, this exempted *"specialty tier"* is determined solely based upon a dollar-per month threshold ($600 per month at present), without regard to clinical or competitive dynamics. CMS claims this specialty tier exception has been *made "in order to ensure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications."* For this specialty tier, cost-sharing is limited to 25% after meeting deductibles. The Relator alleges that this broad exception for specialty drugs has made it quite easy for the PBM Defendants to avoid employing cost-saving branded *"therapeutic substitution"* programs in crowded specialty drug areas and to collude with manufacturers in passing massive price increases onto sponsors and beneficiaries. The use of high-price as the sole criteria for inclusion in the exempted specialty tier enables the PBM Defendants to easily include all drugs in crowded therapeutic areas (such as multiple sclerosis and rheumatoid arthritis) in the formulary with similar reimbursement status, without little risk of scrutiny. In turn, the PBM Defendants are free to forge confidential financial terms with all specialty drug manufacturers in crowded therapeutic categories.

303. Consistent with CMS formulary guidelines, a review of the 2013 Part D specialty drug formularies for the leading PBMs, Express Scripts, CVS Caremark and Catamaran indicates nearly identical product offerings. In the key specialty drug categories with numerous similar therapeutic options, namely multiple sclerosis, rheumatoid arthritis and chronic myelogenous leukemia, virtually all of the marketed drugs are listed as available, without regard to preference. See **Exhibit 56**. The one exception is in the Catamaran formulary where Avonex, Copaxone and Rebif in the MS area and Enbrel and Humira in rheumatoid arthritis category are listed as *"preferred agents"*. However, these designations by Catamaran apparently have no cost-savings implications for Medicare beneficiaries, since the Relator has already documented virtually identical pricing for these three Manufacturer Defendants MS drugs across part D plans administered by all PBMs. Rather the *"preferred"* status may reflect better financial terms with the manufacturer for Catamaran.

304. On the positive side, CMS clearly empowers Part D plan sponsors (and their surrogates, such as PBMs) to employ all drug cost-saving management tools (i.e., drug tiering, drug exclusion, prior authorization and step therapy) in the management of most specialty drugs. CMS only requires that each *"category or class must include at least two drugs (unless only one drug is available for a particular category or class, or only two drugs are available but one drug is clinically superior to the other for a particular category or class)…"* Furthermore, when developing their formulary tier structure, CMS states that *"sponsors should utilize standard industry practices….Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary." Medicare Prescription Drug Manual, Section 30.2.7, page 25*. CMS further states, it will ensure that *"sponsors use of such tools is*

consistent with best practices." Unfortunately, Part D formulary regulations regarding specialty drugs have facilitated the PBM Defendants' avoidance of these well-established cost-saving tactics as part of the collusive with the specialty drug manufacturers.

SHROUDING THE FRAUD FROM PUBLIC SCRUTINY

A. Medicare Part D Low-Income Subsidies (LIS) and Patient Assistance Programs (PAPs)

305. In an April 2011 article in *Neurology Today,* several leading MS clinicians voiced their concern regarding the burden of rising MS drug costs. *Neurology Today, 21 April 2001, Vol 11, Issue 8, pages 1,19,23.* Edward Fox, MD, PhD, Professor of Neurology at the University of Texas and Director MS clinic of Central Texas, stated: *"On a weekly basis, I'm dealing with patients who have what I would call a medication crisis...many of my patients have co-pays of between $300 and $800 a month. There aren't too many families who can easily absorb that cost". Bruce* Cohen, MD, professor of Neurology and Director of the Comprehensive Multiple Sclerosis Program at Northwestern University, added that he had a *"number of patients who are making treatment decisions based primarily on cost."* However, Dr. Fox countered that cost-based decision were increasingly difficult because *"It's become an across the board situation where all the MS medications are so expensive that you can't just switch to a less costly alternative."* Robert Lisak, MD, Professor and Chair of the Department of Neurology at Wayne State University stated: *"I just saw a patient yesterday whose husband makes too much money for compassionate care, but his insurance plan does not cover his wife's MS drugs...the companies will only help so much."* However, despite isolated cases of concern, public scrutiny of the unprecedented US MS specialty drug price inflation has remained relatively modest in the seven years since the start of Medicare Part D. As discussed previously, the Relator has determined that cost insulation in the LIS Part D population and the aggressive increase in Manufacturer Patient Assistance Program (PAP) funding have been key factors enabling the price collusion outlined in this complaint.

306. Unfortunately, CMS does not appear to require manufacturers to disclose details of their PAP programs. Among the Manufacturer Defendants, Biogen has reported more than a tripling of patient financial assistance from $100 million in 2007 to $353 million in 2012. *Biogen Annual Reports, 2007-2012.* These amounts are for Biogen's overall product portfolio, although the MS therapy, Avonex, the company's largest product, undoubtedly accounts for a significant portion of the spending. Given intense competition and similar pricing action among the other older MS therapies, a similar escalation in financial support has no doubt occurred at the other Manufacturer Defendants. However, none of the other Manufacturer Defendants publicly discloses PAP financial data relevant to the MS area. Another clear sign of escalating specialty drug support is the increased corporate funding of *"independent"* charities that provide patient financial assistance. A notable

example is the Chronic Disease Fund which was formed in 2005 (funded primarily by manufacturers) with the express purpose of providing *"co-payment support for specialty therapeutics"* for both private and Medicare Part D plans in the United States. Since its founding, Chronic Disease Fund US specialty drug co-payment support has increased from $5 million in 2005 to $196 million in 2011, the latest year with available financial statements. *Chronic Disease Fund, Inc., Financial Statements and Independent Auditors' Reports, 2005-2011.*

307. Recent Medicare Part D legislative changes will further decrease beneficiary exposure to out-of-pocket expenses and appear highly beneficial to drug manufacturers. First, the Patient Protection and Affordable Act of 2010 established a manufacturer Discount Program to help non-LIS Medicare Part D beneficiaries with their prescription drug costs during the coverage gap (i.e., *"Doughnut Hole"*). Until the Discount Program began in 2011, beneficiaries were required to pay 100% of drug costs in the coverage gap. The Discount Program requires manufacturers to provide a 50% discount off the price for brand-name drugs in the gap. While manufacturer discounts during the coverage gap undoubtedly benefit many elderly beneficiaries, the program has also likely contributed to further severe drug price inflation for several reasons. First, manufacturers, with cooperation from the dominant PBM Defendants, may accelerate price increases in Part D to recoup revenues/profits from the discounts.

308. In September 2012, the GAO released a report *(GAO-12-914)* requested by Congress regarding the effect of the Discount Program on brand-name pricing trends. As part of the analysis, the GAO interviewed plan sponsors, PBMs and manufacturers; unfortunately the names of the organizations were not disclosed in the report. Six of the seven large plan sponsors (representing 68% of US Part D enrollees) and two of the three PBMs interviewed as part of the analysis said they thought the Discount Program *"may have been a contributing factor in the rising prices of brand-name drugs by some manufacturers"*. In contrast, six of the eight manufacturers *"believe that the prices of their brand-name drugs negotiated with plan sponsors and PBMs have not been affected by the Discount Program"*. Not surprising and consistent with the Relator's analysis, the PBMs indicated no role in the associated price inflation.

309. The further acceleration in price increases in recent years for the Manufacturer Defendants' MS drugs is supportive of an impact from the Gap Discount Program. In Medicare Part D, the annual per patient cost of Biogen's Avonex rose more than 70% from the $12-14,000 range in 2005 to the $22,000 range in 2008, according to the GAO analysis in its January 2010 specialty drug report. However, the Part D price inflation for the Defendants' MS drugs has been even more severe in subsequent years, with the annual cost per patient in the $54-60,000 range by the end of 2013 for the long-marketed drugs.

310. The Gap Discount Program also states *that "both the portion of drug costs for brand-name drugs paid by the (non-LIS) beneficiary and the portion paid by the manufacturer count toward reaching the*

beneficiary's annual catastrophic coverage threshold". While this stipulation significantly decreases beneficiary out-of-pocket costs, it also benefits manufacturers in important ways. First, manufacturers obviously are incentivized to increase prices to accelerate reaching the Catastrophic threshold. Second, by *"crediting"* manufacturers for the discount, CMS is decreasing the need and associated economic cost for manufacturers to provide future PAP support to many non-LIS Part D beneficiaries.

311. Two other aspects of the ACA legislation will make the benefit more generous to beneficiaries and more costly to CMS and general taxpayers in the coming years. First, the annual out-of-pocket threshold will only increase in line with the CPI (plus 2%) through 2020, which is far lower than recent Medicare Part D brand drug price inflation and program spending trends. Second, beneficiary cost-sharing during the gap period will decrease from 47.5% in 2013 to 25% in 2020, further increasing the federal government's share of Medicare Part D program costs.

312. On March 21st, 2004, the Department of Health and Human Services (HHS) issued a press release to highlight the considerable cost savings and improved benefits that many Part D beneficiaries have enjoyed in the four years since the signing of the Affordable Care Act into law. In the release, HHS specifically identified the considerable drug cost savings as a result of the manufacturer *"Donut Hole"* Gap Discount program. According to HHS, *"7.9 million senior and people with disabilities have saved $9.9 billion on prescription drugs, or an average of $1,265 per beneficiary since the passage of the discount program. In 2013 alone, 4.3 million seniors and people with disabilities saved $3.9 billion, or an average of $911 per beneficiary. These figures were even higher than in 2012, when 3.5 million beneficiaries saved $2.5 billion, for an average of $706 per beneficiary."* In the release, HHS also provided a table with a breakdown of the savings by State. While many Part D beneficiaries have undoubtedly benefited from the Gap Discount program, this data is quite misleading since most of these Gap Discount savings have likely been largely offset by the ongoing severe inflation of many specialty therapies and other branded drugs in Part D. In the case of the Manufacturer Defendants MS drugs, the massive ongoing inflation has far outstripped the well-intentioned goals of the program. The annual cost per year for the Manufacturer Defendants MS drugs has nearly doubled from the $30,000 range in 2010 just before the discount program began to $55-60,000 at the present time. As such, the Manufacturer Defendants (in collusion with the PBM Defendants) will gladly pay the 50% discount off these vastly-inflated prices in the narrow *"Donut hole"* window, while reaping the financial benefit of the extreme price increases elsewhere in Part D.

B. Inaccurate Medicare Part D Spending Forecast

313. Corporate interests, as well as supportive politicians and trade organizations (such as those affiliated with Pharmaceutical and PBM industries) cite the fact that the costs of Medicare Part D have been

less than predicted prior to its start as a *"definitive"* indication of the program's *"free market"* success. However, the Relator's investigation has determined that the entire premise for these success claims is based upon a very *"broadbrush"* Part D spending forecast by the Congressional Budget Office (CBO), for which full analytical details have never been publicly-disclosed. Following a request from the Committee on the Budget of the US Senate, on November 20, 2003, the CBO Director, Douglas Holtz-Eakin sent the Senate Committee's Chairman, Don Nickles, a letter providing its forecast for Part D spending for the years 2006 through 2013. The forecast also included expected State *"Clawback"* payments to help fund *"dual eligibles"* switched to Medicare Part D and the related impact on State Medicaid drug spending budgets. *Letter from CBO Director Douglas Holtz-Eakin to Senator Don Nickles, November 20, 2013.* In Table 1 of the document, CBO forecasted total Part D spending of $26 billion in 2006, rising to $73 billion in 2013. The CBO forecasted LIS Subsidy payments of $9 billion in 2006, rising to $35 billion in 2013. Initial State *"Clawback"* payments were forecasted at $6 billion in 2006, rising by exactly $1 billion/year to $15 billion in 2013. The document does not provide estimates of Part D enrollment by year, but a footnote in Table 1 states that CMS expected an *"average"* of 73% of Medicare beneficiaries between 2006 and 2013 to receive their prescription drug coverage through Part D. Of note, CBO also forecasted that the beneficiary annual out-of-pocket spending limit would rise steadily from $3,600 initially in 2006 to $6,400 in 2013. Finally, in Table 4, the CBO estimated that 12.2 million Medicare beneficiaries would be eligible for Low-Income Studies, including 6.4 million initial State *"Dual Eligibles"*.

314. In reality, as soon as the Part D program commenced, all of these *"broadbrush"* CBO forecasts, with the exception of the number of State *"dual eligible"* enrollees, proved to be grossly over-estimated. While some details of the CBO analytical assumptions have filtered into the public domain, the Relator has not been able to locate the full details of the CBO analysis. As discussed below, the overly-aggressive Part D forecast, not effective *"private market"* competition, was the primary reason for significantly under-forecast spending in the early years of the Part D program. Most importantly, the CBO failed to account for massive major traditional drug patent expirations, of which the pharmaceutical industry, the investment community and the media were all well aware. Despite the huge forecast miscalculation, the Relator has found no evidence that Federal authorities have ever publicly released a re-assessment of the initial CBO forecast. Rather, to the present day, corporate interests, as well as related trade organizations and lobbying groups, continue to site the initial inaccurate CBO forecast as the basis for Part D's *"overwhelming"* success. This self-serving and misleading characterization has been essential in deflecting scrutiny from the severe price collusion in Part D for numerous specialty drugs, including for the Defendants' MS therapies. The Relator believes that a full investigation of the initial CBO Part D forecast should be part of the discovery related to this case.

315. According to a recent Medicare Trustee Report, the actual net Part D spending has been about 30% lower than the initial projections made by the Congressional Budget Office (CBO) in 2003. Industry

supporters attribute the lower spending to efficiencies produced by competition among the private insurers that deliver the drug benefit. *House Budget Committee Chairman Paul Ryan's March 20, 2012 address to the American Enterprise Institute.*

316. However, independent research clearly indicates that this *"private market success"* characterization of the Medicare Part D program is quite misleading for a variety of reasons. In fact, the analysis suggests the lower than expected spending pertains largely to external factors unrelated to Part D private plan competition, as well as overly-aggressive initial forecasts. Key factors contributing to the lower than expected Medicare Part D spending included:

1) Lower than expected Medicare Part D enrollment: According to the Medicare Trustees, between 2006 and 2010, actual average enrollment was 10.6 million or 25% less than had been estimated by the CBO in when Congress enacted Part D. *Center for Budget Policy Priorities report, 5/14/2012.*

2) The growth of both public and private spending on prescription drugs had slowed considerably since the CBO's 2003 projections. In its initial forecast, CBO assumed average annual US per capita growth in drug spending of 9% after 2006, while the actual growth was 4%. *Medicare Spending Trends, Kaiser Family Foundation, May 2012.* As a result, actual Part D costs per beneficiary in 2010 were 16% lower than the CBO had estimated. System wide pharmaceutical spending was lower than expected because major drugs went off patent, the use of lower-cost generics increased substantially and fewer new drugs reached the market, none of which were preferentially beneficial to the Part D program.

317. More recently, a review of the Medicare Part D program by the IMS Institute provided further validation. For the years 2006 through 2010, IMS calculated that the average daily cost of therapy for the top 10 Medicare Part D traditional therapeutic categories by volume (including agents for high cholesterol, hypertension, depression and GI ulcers) declined by an average of 30% between 2006 and 2010, due to patent expiration and increased generic utilization. Consistent with these findings, as noted previously, the "Direct Subsidy" per enrolled beneficiary in Part D declined 24% between 2006 and 2013. In fact, given the price erosion in the traditional pharmaceutical sector, overall Part D drug spending and premium trends would likely have declined in Part D if not for massive price inflation of many leading specialty drugs.

318. As noted previously, the drug spending has risen dramatically for 6 million low-income, *"dual-eligible"* beneficiaries who were switched from Medicaid to Medicare Part D as part of the MMA legislation. In fact, a recent CBO report estimated that requiring private plans access to the same rebates as in Medicaid would reduce Part D costs by $137 billion over the next ten years. *CBO Estimate of the Effects of Medicare,*

Medicaid and Other Mandatory Health Provisions in the President's Budget Request for Fiscal Year 2013, March 16, 2012.

319. While Medicare Part D costs to date have been below initial aggressive targets, spending in the program is expected to accelerate considerably in the coming years. According to the 2013 Medicare Trustee Annual Report, between 2006 and 2013, Medicare Part D overall spending and *"spending per enrollee"* grew at a 6% and 1% average annual rate, respectively. Going forward, the Trustees expect overall Part D spending to average 10% per year, with spending per enrolled rising 7% annually. Overall, the Trustees forecast Medicare Part D spending to nearly triple from $66.9 billion in 2012 to $165.2 billion in 2022. While the Trustees cited fewer patent expiries and increased enrollment as factors in the spending re-acceleration, specialty drugs will undoubtedly be the key driver of growth. After recent modest trends, Part D spending per enrollee is expected to increase from $1,793.57 in 2012 to $3,297.41 in 2022. See **Exhibit 57**.

320. Furthermore, the re-acceleration is expected to begin near term. In the report, the Trustees indicated that they already expect the Medicare Part D program to be over-budget by about $4 billion for 2013, which will be added to the 2014 budget. As such, after an 8% increase in Part D spending to $72.2 billion in 2013, the program is forecasted to increase 16% in 2014 to $83.6 billion.

C. The Dominant Manufacturer funding of MS Patient Advocacy Organizations

321. While the industry apathy towards escalating MS drug prices is easy to understand, the relative quiescence of other MS constituents is concerning. For instance, given the considerable financial burden placed on many MS patients by the massive price inflation, one might expect the nation's largest MS patient advocacy organization, the National Multiple Sclerosis Society (NMSS), to devote considerable attention to these disturbing trends. Many analyses in recent years, including surveys sponsored by the PBM Defendants in this case, indicate that higher drug prices and increased patient cost-sharing responsibilities often prevent patient access to essential medications. *2012 Specialty Drug Benefit Report from the Pharmacy Benefit Management Institute (PBMI), page 17.*

322. However, a Relator review of the NMSS website found no specific mention of severe MS drug price inflation. In its website, the NMSS also appears careful to limit the visibility of the MS drug manufacturers. Under the *"Sources of Support"* section, the organization states that drug companies provide *"direct support"* that accounts for only 4% of its annual budget. The Society states that 96% of its budget comes from *"Special Events"* and *"Individual Giving"*. Unfortunately, the annual statements of the organization filed with the IRS do not provide any granularity on these large donation categories. However, further delving in the website indicates that corporate sponsors play a major role as financial sponsors for

virtually all *"Special Events"*, such as Bikathons and Walkathons, which accounted for 65% of the organization's annual budget in 2011. *National MS Society Website.* As such, the Relator suspects that MS drug manufacturers actually account for a majority of the NMSS's nearly $100 million annual budget. *Combined Financial Statements; National Multiple Sclerosis Society; Year ended September 30, 2011.* While the NMSS provides strong MS support in many areas, such as education and research, its failure to address extreme pricing trends is a glaring omission.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE

False Claims Act

31 U.S.C. §§3729(a)(l) and (a)(2)

(Against All Defendants)

323. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

324. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

325. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval, within the meaning of 31 U.S.C. §3729(a)(1).

326. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2).

327. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

328. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

329. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO

False Claims Act

31 U.S.C. §3729(a)(3)

(Against All Defendants)

330. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

331. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

332. By virtue of the acts described above, Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims, within the meaning of 31 U.S.C. §3729(a)(3). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

333. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

334. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every violation of 31 U.S.C. §3729(a)(3) as described herein.

COUNT THREE

Federal False Claims Act

31 U.S.C. §3729(a)(7)

(Against All Defendants)

335. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as

though fully set forth herein.

336. This is a claim for penalties and treble damages under the Federal False Claims Act.

337. By virtue of the acts described above, including without limitation Defendants' overpayment of BFSFs in lieu of rebates, which would have reduced the ultimate cost reimbursed by the federal government under Medicare Part D, to Service Vendors, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

338. As a result, money was lost to the United States through the non-payment or non-transmittal of money from foregone discounts and rebates to which the United States was entitled and owed by the Defendants, and other costs were sustained by the United States.

339. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

340. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

COUNT FOUR

Federal False Claims Act

31 U.S.C. §§3729(a)(l) and (a)(2)

(Against All Defendants)

341. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

342. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

343. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for

payment and/or approval, within the meaning of 31 U.S.C. §3729(a)(1) by paying BFSFs as illegal remuneration to Service Vendors (primarily PBMs and their specialty pharmacy subsidiaries in Medicare Part D) in order to induce purchase of Defendants' MS drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

344. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid and/or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2) by paying BFSFs as illegal remuneration to induce Service Vendors to purchase MS drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

345. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

346. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

347. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT FIVE

California False Claims Act Cal Gov't.

Code §12651(a)(7)

(Against All Defendants)

348. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

349. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of California via Federally-mandated, non-recourse *"Clawback"*

payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

350. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California, within the meaning of Cal Gov't. Code §12651(a)(7). The State of California has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIX

Colorado Medicaid False Claims Act

Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310

(Against All Defendants)

351. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

352. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Colorado via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

353. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Colorado. The State of Colorado has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVEN

Connecticut False Claims Act

Conn. Gen. Stat. § 17b-301b(a)(7)

(Against All Defendants)

354. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

355. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Connecticut via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

356. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Connecticut, within the meaning of Conn. Gen. Stat. § 17b-301b(a)(7). The State of Connecticut has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHT

Delaware False Claims And Reporting Act

6 Del Code §1201(a)(7)

(Against All Defendants)

357. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

358. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Delaware via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

359. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Delaware, within the meaning of 6 Del. Code §1201(a)(7). The State of Delaware has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINE

Florida False Claims Act

Fla. Stat. Ann. §68.082(2)(g)

(Against All Defendants)

360. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

361. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Florida via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

362. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Florida, within the meaning of Fla. Stat. Ann. §68.082(2)(g). The State of Florida has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TEN

Georgia False Medicaid Claims Act

Ga. Code Ann. §49-4-168.1(7)

(Against All Defendants)

363. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

364. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Georgia via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

365. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Georgia, within the meaning of Ga. Code Ann. §49-4-168.1 (7). The State of Georgia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT ELEVEN

Hawaii False Claims Act

Haw. Rev. Stat. §661-21(a)(7)

(Against All Defendants)

366. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

367. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Hawaii via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

368. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Hawaii, within the meaning of Haw. Rev. Stat. §661-2l(a)(7). The State of Hawaii has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWELVE

Illinois Whistleblower Reward And Protection Act

740 Ill. Comp. Stat. §175/3(a)(7)

(Against All Defendants)

369. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

370. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Illinois via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

371. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois, within the meaning of 740 Ill. Comp. Stat. §175/3(a)(7). The State of Illinois has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTEEN

Indiana False Claims and Whistleblower Protection Act

IC 5-11-5.5-2(b)(6)

(Against All Defendants)

372. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

373. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

374. By vi1iue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Indiana, within the meaning of IC 5-11-5.5-2(b)(6). The State of Indiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FOURTEEN

Iowa False Claims Act

Iowa Code §§ 685.1 through 685.7

(Against All Defendants)

375. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

376. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

377. By vi1iue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Iowa. The State of Iowa has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FIFTEEN

Louisiana Medical Assistance Programs Integrity Law

La. Rev. Stat.§ 46:438.3(C)

(Against All Defendants)

378. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

379. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Louisiana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

380. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Louisiana, within the meaning of La. Rev. Stat. § 46:438.3(C). The State of Louisiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIXTEEN

Maryland False Health Claims Law

Health-Gen. & 2-602 (a) (1), (2)

(Against All Defendants)

381. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

382. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Maryland via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

383. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Maryland, within the meaning of MD Code Ann., Health-Gen. § 2-602 (a) (1), (2). The State of Maryland has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVENTEEN

Massachusetts False Claims Law

Mass. Gen. Laws ch. 12 §5B(8)

(Against All Defendants)

384. Relator repeats and realleges each and every allegation contained in the paragraphs above

as though fully set forth herein.

385. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Massachusetts via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

386. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts, within the meaning of Mass. Gen. Laws ch. 12 §5B(8). The Commonwealth of Massachusetts has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHTEEN

Michigan Medicaid False Claims Act

§400.607(3)

(Against All Defendants)

387. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

388. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Michigan via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

389. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Michigan, within the meaning of §400.607(3). The State of Michigan has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for

each false claim.

COUNT NINETEEN

Minnesota False Claims Act

Minn. Stat. §§ 15C.01 through 15C.16

(Against All Defendants)

390. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

391. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Minnesota via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

392. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Minnesota. The State of Minnesota has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY

Montana False Claims Act

Mont. Code Ann. 17-8-403(1)(g)

(Against All Defendants)

393. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

394. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to

fraudulent overpayment by the State of Montana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

395. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Montana, within the meaning of Mont. Code Ann. 17-8-403(1)(g). The State of Montana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-ONE

Nevada Submission of False Claims to State or Local Government Act

Nev. Rev. Stat. Ann. §357.040(1)(g)

(Against All Defendants)

396. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

397. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Nevada via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

398. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Nevada, within the meaning of Nev. Rev. Stat. Ann. §357.040(l)(g). The State of Nevada has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-TWO

New Hampshire False Claims Act

N.H. Rev. Stat. Ann. §167:61-b(l)(e)

(Against All Defendants)

399. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

400. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Hampshire via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

401. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Hampshire, within the meaning of N.H. Rev. Stat. Ann. §167:61-b(I)(e). The State of New Hampshire has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-THREE

New Jersey False Claims Act

N.J. Stat. §2A:32C-3(g)

(Against All Defendants)

402. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

403. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as

conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Jersey via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

404. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Jersey, within the meaning of N.J. Stat. §2A:32C-3(g). The State of New Jersey has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FOUR

New Mexico Medicaid False Claims Act

N.M. Stat. Ann.§ 27-14-3(a)(7)

(Against All Defendants)

405. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

406. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Mexico via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

407. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Mexico, within the meaning of N.M. Stat. Ann. § 27-14-3(a)(7). The State of New Mexico has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FIVE

New York False Claims Act

NY CLS St. Fin. §189(g)

(Against All Defendants)

408. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

409. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New York via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

410. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New York, within the meaning of NY CLS St. Fin. §189(g). The State of New York has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENT-SIX

North Carolina False Claims Act

2009-554 N.C. Sess. Laws §1-607(a)(7)

(Against All Defendants)

411. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

412. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of North Carolina via Federally-mandated, non-recourse *"Clawback"*

payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

413. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of North Carolina, within the meaning of 2009-554 N.C. Sess. Laws §1-607(a)(7). The State of North Carolina has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-SEVEN

Oklahoma Medicaid False Claims Act

Okla. Stat. tit. 63, §5053.1B (7)

(Against All Defendants)

414. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

415. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Oklahoma via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

416. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Oklahoma, within the meaning of Okla. Stat. tit. 63, §5053.1B (7). The State of Oklahoma has thereby suffered actual damages and is entitled to recover treble Oklahoma damages and a civil penalty for each false claim.

COUNT TWENTY-EIGHT

Rhode Island State False Claims Act

R.I. Gen. Laws §9-1.1-3(7)

(Against All Defendants)

417. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

418. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Rhode Island via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

419. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Rhode Island, within the meaning of R.I. Gen. Laws §9-1.1-3(7). The State of Rhode Island has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-NINE

Tennessee False Claims Act and

Medicaid False Claims Act

Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(l)(D)

(Against All Defendants)

420. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

421. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to

fraudulent overpayment by the State of Tennessee via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

422. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Tennessee, within the meaning of Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-18l(a)(l)(D). The State of Tennessee has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY

Texas Medicaid Fraud Prevention Act

Tex. Hum. Res. Code Ann. §36.002(12)

(Against All Defendants)

423. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

424. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Texas via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

425. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Texas, within the meaning of Tex. Hum. Res. Code Ann. §36.002(12). The State of Texas has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-ONE

Virginia Fraud Against Taxpayers Act

Va. Code Ann. §8.01-216.3(a)(7)

(Against All Defendants)

426. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

427. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Virginia via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

428. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Virginia, within the meaning of Va. Code Ann. §8.01-216.3(a)(7). The Commonwealth of Virginia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-TWO

Washington Medicaid Fraud False Claims Act

Wash. Sess. Laws, Laws of 2012

Ch. 241 §§ 201 through 214

(Against All Defendants)

429. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

430. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as

conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Washington via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

431. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Washington. The State of Washington has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-THREE

Wisconsin False Claims For Medical Assistance Act

Wis. Stat. §20.931(2)(g)

(Against All Defendants)

432. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

433. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Wisconsin via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

434. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Wisconsin, within the meaning of Wis. Stat. §20.931(2)(g). The State of Wisconsin has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-FOUR

District of Columbia False Claims Act D.C. Code Ann. §2-308.14(a)(7)

(Against All Defendants)

435. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

436. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the District of Columbia via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

437. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia, within the meaning of D.C. Code Ann. §2-308.14(a)(7). The District of Columbia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-FIVE

Unjust Enrichment

438. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

439. By virtue of their conduct, Defendants have been unjustly enriched at the expense of the United States. By obtaining money as a result of their violations of federal law, Defendants were unjustly enriched, and are liable to account and pay such amounts to be determined at trial.

440. By this claim, Relator demands a full accounting of all BFSFs (and interest thereon) incurred and/or paid by the Manufacturer Defendants to the PBM Defendants for services and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States.

COUNT THIRTY-SIX

Common Law Fraud

441. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

441. Manufacturer Defendants made or caused to be made material and false representations concerning the calculation, for which they are responsible, of the BFSFs that were paid to the PBM Defendants for services that CMS requires be provided at FMV, which representations were made by Service Vendors for Services that CMS requires be provided at FMV, with knowledge of their falsity or with reckless disregard for the truth. The PBM Defendants then knowingly submitted false claims for payment to the United States to act upon those misrepresentations to the United States' detriment. The United States acted in justifiable reliance upon both the Manufacturer Defendants and the PBM Defendants misrepresentations by making payments on the false claims.

442. Had the Manufacturer Defendants and the PBM Defendants made truthful statements, the United States would not have made payments for excessive prices for the Manufacturer Defendants' multiple sclerosis drugs in Medicare Part D.

443. As a direct and proximate cause of Defendants' conduct, the United States has been damaged in an amount to be determined at trial.

PRAYERS FOR RELIEF

444. WHEREFORE, the Relator acting on behalf of and in the name of the United States of America, and on his own behalf, demands and prays that judgment be entered as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.*, and the Anti-Kickback Statute as set forth above;

B. That this Court enter judgment in favor of the United States against the Defendants jointly and severally in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not Eleven Thousand Dollars ($11,000) for each false claim;

C. In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

D. In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of the Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by the Relator;

E. In favor of the Relator and the United States and against the Defendants for all costs of this action;

F. In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable.

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §1651(a);

H. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310;

I. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Conn. Gen. Stat. § 17b-301b;

J. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

K. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082(2);

L. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil

penalty of $11,000 for each violation of Ga. Code Am1. §49-4-168.1.

M. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-2l(a);

N. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

O. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of IC 5-11-55;

P. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty of at least $10,000 for each violation of Iowa Code §§ 685.1 through 685.7;

R. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

S. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MD Code Ann., Health-Gen. § 2-602 (a) (1). (2);

T. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

U. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MI Public Act 337;

V. That this Court enter judgment against Defendants in an amount equal to three times the

amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Minn. Stat. §§ 15C.01 through 15C.16;

W. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants ' actions, plus a civil penalty of $10,000 for each violation of Mont. Stat. Ann. 17-8-401;

X. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

Y. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus civil penalties for each violation of N. H. Rev. Stat. Ann. §167:61-b(l);

Z. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of N.J. Stat. §2A:32C-3;

AA. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

BB. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of NY CLS St. Fin. §189;

CC. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty or $11,000 for each violation of 2009-554 N.C. Sess. Laws §1- 607(a);

DD. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63, §5053.1B;

EE. That this Court enter judgment against Defendants in an amount equal to three times the

amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws §9-1.1-3;

FF. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(l);

GG. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

HH. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Va. Code Ann. §8.01-216.3(a);

II. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat. §20.931(2);

JJ. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214;

KK. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §2-308.14(a);

LL. That Relator be awarded the maximum amount allowed pursuant to§3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

MM. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

NN. That Relator recovers such other relief as the Court deems just and proper.

JURY DEMAND

445. Plaintiff/Relator demands a trial by jury on all counts.

Dated: May 1, 2014

Respectfully Submitted,
RELATOR John R. Borzilleri, M.D.

_____

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_____

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CERTIFICATE OF SERVICE

Pursuant to 31 U.S.C. §3730(b)(2) and Federal Rule of Civil Procedure 4(d)(4), on this 10th Day of January 2014, I caused a true and correct copy of this Complaint to be served upon Zachary Cunha, Assistant United States Attorney at the Office of the United States Attorney, District of Rhode Island at 50 Kennedy Plaza, 8th Floor, Providence, RI 02903

Regis A. Shields, Esq. Connecticut Attorney ID: 305483

APPENDIX: LIST OF EXHIBITS

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2. Estimated Manufacturer/PBM Defendant MS BFSF Fee Fraud: 2006-2013
3. US Multiple Sclerosis Market for Manufacturer Defendant Drugs: 2005-2013
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5. Medicare Part D Enrollment & Reimbursement: 2006-2012
6. Share of Medicare Part D Reimbursement: 2006-2012
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8. Medicare Part D PAP and Plan Sponsor Cost Assistance
9. Medicare Part D Catastrophic Spending/Cost-Sharing
10. Medicare Part D LIS Enrollment and Subsidies: 2006-2012
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45. US Specialty Drug Market: Price Increases as Primary Growth Driver: 2008-2013
46. Leading US Medicare Specialty Drug Category Trends: 2010-2013
47. US Multiple Sclerosis Market: Massive Price Increases Driving Growth
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51. Express Scripts: Specialty Drugs as Key Growth Driver
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Exhibit 1

US Multiple Sclerosis Drug Pricing Trends

Unprecedented Massive Price Inflation since 2006 Start of Medicare Part D

US Annual Cost/Patient ($)	2005	2006	2007	2008	2009	2010	2011	2012	Jan 2013	Dec 2013	Change 2005-2013
Avonex (Biogen)	$12,400	$14,300	$16,300	$22,000	$29,900	$32,100	$37,550	$42,400	$51,000	$59,090	377%
Copaxone (Teva)	10,800	12,150	16,650	19,000	25,200	30,470	36,800	42,300	56,000	56,020	419%
Rebif (Pfizer)	12,400	13,350	18,300	21,000	28,300	32,200	33,900	37,000	53,300	62,870	407%
Betaseron (Bayer)	10,800	11,800	17,200	21,000	26,700	31,970	37,280	42,100	51,700	56,020	419%
Exantia (Novartis)	-	-	-	-	24,000	28,773	33,552	37,890	46,530	50,418	-
Average	$11,600	$12,900	$17,113	$20,750	$27,525	$31,685	$36,383	$40,950	$53,000	$58,500	404%
		11%	33%	21%	33%	15%	15%	13%	29%	10%	

Annual US Price Increase	2005	2006	2007	2008	2009	2010	2011	2012	Jan 2013	Dec 2013	Change 2012-2013
Avonex (Biogen)	-	15%	14%	35%	36%	7%	17%	13%	20%	16%	39%
Copaxone (Teva)	-	13%	37%	14%	33%	21%	21%	15%	32%	0%	32%
Rebif (Pfizer)	-	8%	37%	15%	35%	14%	5%	9%	44%	18%	70%
Betaseron (Bayer)	-	9%	46%	22%	27%	20%	17%	13%	23%	8%	33%
Exantia (Novartis)	-	-	-	-	-	20%	17%	13%	23%	8%	33%
Average	-	11%	33%	21%	33%	15%	15%	12%	30%	11%	43%

Source: PriceRx, CMS, various brokerage reports.

Exhibit 2

US Multiple Sclerosis Market: 2005 to 2013

Massive Price Increases and Declining Volume

Fuels Exponential Growth in Fraudulent BFSFs from Manufacturer Defendants

	2005	2006	2007	2008	2009	2010	2011	2012	2013	Change 2005-2013
US Sales ($mil)[1]										
Avonex (Biogen)	$826	$920	$987	$1,168	$1,294	$1,380	$1,514	$1,677	$1,778	115%
Copaxone (Teva)	688	824	996	1261	1764	2115	2597	2712	3016	294%
Rebif (EMD Serono/Pfizer)	343	444	632	713	865	921	1006	1122	1189	227%
Betaseron (Schering)	327	360	424	509	613	577	578	589	601	80%
Extavia (Novartis)	-	-	-	-	7	14	23	27	33	-
Combined US Sales ($mil)	$2,185	$2,548	$3,038	$3,651	$4,542	$5,008	$5,719	$6,127	$6,618	203%
Growth	-	17%	19%	20%	24%	10%	14%	7%	8%	
Estimate US-Treated Patients										
Avonex (Biogen)	66,639	64,322	60,574	53,112	43,262	42,982	40,328	39,554	32,308	-52%
Copaxone (Teva)	63,719	67,852	59,792	66,362	69,986	69,428	70,584	64,102	53,853	-15%
Rebif (EMD Serono/Pfizer)	27,677	33,236	34,510	33,942	30,558	28,612	29,683	30,324	20,476	-26%
Betaseron (Schering)	30,311	30,508	24,655	24,226	22,948	18,054	15,492	13,992	11,155	-63%
Extavia (Novartis)	-	-	-	-	307	482	693	711	675	-
Combined Treated Patients	188,346	195,918	179,531	177,641	167,061	159,559	156,780	148,683	118,467	-37%
Est. US PBM BFSFs (4%, $)										
Avonex (Biogen)	$33	$37	$39	$47	$52	$55	$61	$67	$71	115%
Copaxone (Teva)	28	33	40	50	71	85	104	108	121	338%
Rebif (EMD Serono/Pfizer)	14	18	25	29	35	37	40	45	48	247%
Betaseron (Schering)	13	14	17	20	25	23	23	24	24	84%
Extavia (Novartis)	-	-	-	-	0.3	1	1	1	1	-
Combined Est. US BFSFs ($mil)	$87	$102	$122	$146	$181	$200	$228	$244	$263	201%
Growth	-	17%	19%	20%	24%	10%	14%	7%	8%	
Est. US BFSF/Patient ($)										
Avonex (Biogen)	$496	$572	$652	$880	$1,196	$1,284	$1,502	$1,696	$2,202	242%
Copaxone (Teva)	$432	$486	$666	$760	$1,008	$1,219	$1,472	$1,692	$2,240	292%
Rebif (EMD Serono/Pfizer)	$496	$534	$732	$840	$1,132	$1,288	$1,356	$1,480	$2,323	198%
Betaseron (Schering)	$432	$472	$688	$840	$1,068	$1,279	$1,491	$1,684	$2,154	290%
Extavia (Novartis)	-	-	-	-	$960	$1,151	$1,342	$1,516	$1,939	-
Average BFSF/US Patient ($)	$464	$516	$685	$830	$1,101	$1,267	$1,455	$1,638	$2,230	253%
Growth	-	11%	33%	21%	33%	15%	15%	13%	36%	

Exhibit 2 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013
Est. Fraudulent US BFSFs ($)									
Avonex (Biogen)	-	$5	$9	$20	$30	$34	$41	$47	$55
Copaxone (Teva)	-	4	14	22	40	55	73	81	97
Rebif (EMD Serono/Pfizer)	-	1	8	12	19	23	26	30	37
Betaseron (Schering)	-	1	6	10	15	15	16	18	19
Extavia (Novartis)	-	-	-	-	0.2	0.3	1	1	1
Combined Est. US BFSF Fraud ($mil)	-	$11	$38	$64	$105	$127	$157	$176	$210
Growth	-	-	243%	68%	64%	21%	23%	13%	19%
Cum. Est. US BFSF Fraud ($mil)	-	$11	$49	$113	$217	$344	$501	$677	$887
Estimated Part D MS Share (%)	-	12%	12%	13%	14%	15%	17%	19%	25%
Est. Med Part D BFSF Fraud ($mil)		$1	$6	$15	$31	$52	$86	$130	$222

[1] Estimated Sales exclude Medicaid and other discounted government programs

Source: Corporate reports, Price Rx, Medispan, brokerage reports and Relator estimates.

Exhibit 3

US Multiple Sclerosis Market: 2005 to 2013

Staggering Magnitude of MS Drug Revenue Fraud

Fueled by Medicare Part D FMV BFSF Fraud

($millions)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	Change 2005-2013
US Sales ($mil)										
Avonex (Biogen)	$939	$1,022	$1,085	$1,277	$1,406	$1,492	$1,628	$1,794	$1,902	103%
Copaxone (Teva)	782	916	1,094	1,378	1,917	2,287	2,793	2,900	3,226	313%
Rebif (Pfizer)	390	493	694	779	940	996	1,082	1,200	1,272	226%
Betaseron (Bayer)	372	400	466	556	666	624	621	630	643	73%
Extavia (Novartis)	-	-	-	-	8	15	25	29	35	-
Combined US Sales ($mil)	$2,483	$2,831	$3,339	$3,990	$4,937	$5,414	$6,149	$6,553	$7,078	185%
Growth	-	14%	18%	19%	24%	10%	14%	7%	8%	-
Estimated Medicaid/Discounted Gov't	12%	10%	9%	9%	8%	8%	7%	7%	7%	-
Est. Annual US Cost/Patient ($)										
Avonex (Biogen)	$12,400	$14,300	$16,300	$22,000	$29,900	$32,100	$37,550	$42,400	$55,045	344%
Copaxone (Teva)	10,800	12,150	16,650	19,000	25,200	30,470	36,800	42,300	56,010	419%
Rebif (EMD Serono/Pfizer)	12,400	13,350	18,300	21,000	28,300	32,200	33,900	37,000	58,085	368%
Betaseron (Bayer)	10,800	11,800	17,200	21,000	26,700	31,970	37,280	42,100	53,860	399%
Extavia (Novartis)	-	-	-	-	24,000	28,773	33,552	37,890	48,474	-
Average Price ($)	$11,600	$12,900	$17,113	$20,750	$26,820	$31,103	$35,816	$40,338	$54,295	368%
Growth	-	11%	33%	21%	29%	16%	15%	13%	35%	
Estimate US-Treated Patients[1]										
Avonex (Biogen)	66,639	64,322	60,574	53,112	43,262	42,982	40,328	39,554	32,308	-52%
Copaxone (Teva)	63,719	67,852	59,792	66,362	69,986	69,428	70,584	64,102	53,853	-15%
Rebif (EMD Serono/Pfizer)	27,677	33,236	34,510	33,942	30,558	28,612	29,683	30,324	20,476	-26%
Betaseron (Bayer)	30,311	30,508	24,655	24,226	22,948	18,054	15,492	13,992	11,155	-63%
Extavia (Novartis)	-	-	-	-	307	482	693	711	675	-
Combined Treated Patients	188,346	195,918	179,531	177,641	167,061	159,559	156,780	148,683	118,467	-37%
Growth	-	4%	-8%	-1%	-6%	-4%	-2%	-5%	-20%	
US Sales w/o Price Increases ($mil)										
Avonex (Biogen)	$939	$798	$751	$659	$536	$533	$500	$490	$401	-57%
Copaxone (Teva)	782	733	646	717	756	750	762	692	582	-26%
Rebif (EMD Serono/Pfizer)	390	412	428	421	379	355	368	376	254	-35%
Betaseron (Bayer)	372	329	266	262	248	195	167	151	120	-68%
Extavia (Novartis)	-	-	-	-	7	9	10	12	15	-
Combined US Sales ($mil)	$2,483	$2,272	$2,091	$2,058	$1,919	$1,833	$1,798	$1,710	$1,357	-45%
Growth	-	-8%	-8%	-2%	-7%	-5%	-2%	-5%	-21%	

Exhibit 3 (Continued)

Estimated Fraudulent Manufacturer Defendant US Drug Sales ($millions)

Medicare Part D and the Commercial Insurance Markets

	2005	2006	2007	2008	2009	2010	2011	2012	2013
US Sales due to Price Fraud ($mil)									
Avonex (Biogen)	-	$224	$334	$618	$870	$959	$1,128	$1,303	$1,501
Copaxone (Teva)	-	183	448	661	1,161	1,537	2,031	2,208	2,644
Rebif (EMD Serono/Pfizer)	-	81	266	358	561	641	714	824	1,018
Betaseron (Bayer)	-	71	200	294	418	429	454	479	522
Extavia (Novartis)	-	-	-	-	-	6	15	17	20
Combined Fraudulent US Sales ($mil)	-	$559	$1,248	$1,932	$3,010	$3,566	$4,327	$4,814	$5,686
Growth	-	-	123%	55%	56%	18%	21%	11%	18%
Cum. US Sales from Price Fraud ($mil)		$559	$1,807	$3,739	$6,749	$10,315	$14,642	$19,455	$25,141
Estimated Part D MS Share (%)	-	12%	12%	13%	14%	15%	17%	19%	25%
Est. Med Part D Fraud/Year ($mil)	-	$68	$151	$253	$424	$538	$739	$926	$1,420
Cum. Med Part D Fraud ($mil)	-	$68	$218	$471	$895	$1,433	$2,172	$3,098	$4,518

[1] Estimated treated patients excludes Medicaid and other discounted government programs.

Source: Corporate reports, Medi-Span, Price Rx, brokerage reports.

Exhibit 4

US Multiple Sclerosis 2013 Market Share Trends

Share of Total Prescriptions

Accelerating Erosion of the Four Defendant MS Drugs

	March 2013	Mid-Dec 2013	Change in Market Share	Year-Year Total Rx Growth Dec 2013
Defendant MS Drugs				
Avonex (Biogen)	**20.3%**	**17.1%**	**-3.2%**	**-30.0%**
Copaxone (Teva)	**35.9%**	**29.5%**	**-6.4%**	**-11.0%**
Rebif (Pfizer)	**13.8%**	**11.4%**	**-2.4%**	**-18.0%**
Betaseron (Bayer)	**7.9%**	**6.2%**	**-1.7%**	**-22.0%**
Total Four Defendants	**77.9%**	**64.2%**	**-13.7%**	**-**
Other Injectables				
Extavia (Novartis)	**0.2%**	**0.3%**	**0.1%**	**0.0%**
Tysabri (Biogen)	**12.0%**	**12.0%**	**0.0%**	**-**
Oral MS Drugs				
Gilenya (Novartis)	**7.8%**	**8.9%**	**1.1%**	**17.0%**
Aubagio (Sanofi)	**2.1%**	**3.0%**	**0.9%**	**-**
Tecfidara (Biogen)	**0.0%**	**11.6%**	**11.6%**	**-**
Total Oral MS Drugs	**9.9%**	**23.5%**	**13.6%**	**2.0%**
Total US MS Market	**100.0%**	**100.0%**		
Overall US MS Rx Growth	**-1 to -3%**	**+1 to +3%**		

Source: IMS

Exhibit 5

Medicare Part D Reimbursement: Share of Program Spending 2006 to 2012

In Private Part D Plans

	All Beneficiaries				
Program Year	Total Enrollment (millions)	Direct Subsidy Per Beneficiary ($)	Annual Program Direct Subsidies ($bil)	Re-Insurance Subsidy Per Beneficiary ($)	Annual Program Re-insurance Subsidies ($bil)
2006	20.3	$867	$17.6	$297	$6.0
2007	24.3	$744	$18.1	$330	$8.0
2008	25.8	$687	$17.7	$366	$9.4
2009	26.9	$702	$18.9	$376	$10.1
2010	28.0	$705	$19.7	$400	$11.2
2011	29.5	$681	$20.1	$468	$13.8
2012	31.8	$658	$20.9	$492	$15.6
Growth 2012 vs. 2006	57%	-24%	19%	66%	160%

	Low-Income Beneficiaries				
Program Year	LIS Enrollment (millions)	LIS Subsidy Per Beneficiary ($)	Annual Program LIS Subsidies ($bil)	Total Part D Reimbursement ($bil)	State Transfers ($bil)
2006	8.3	$1,817	$15.1	$38.7	$5.5
2007	9.2	$1,820	$16.7	$42.8	$6.9
2008	9.7	$1,856	$18.0	$45.2	$7.1
2009	10.0	$1,955	$19.6	$48.5	$7.6
2010	10.4	$2,020	$21.0	$51.9	$4.0
2011	10.6	$2,104	$22.3	$56.2	$7.1
2012	11.0	$2,053	$22.6	$59.2	$8.4
Growth 2012 vs. 2006	33%	13%	50%	53%	53%

Source: 2013 Annual Report from the Medicare Trustees.

Exhibit 6

Medicare Part D: 2006 to 2012

Share of Program Reimbursement

	Direct Subsidies	LIS Subsidies	Re-insurance Subsidies	Combined LIS/Re-insurance Subsidies	State "Clawbacks" as % of Total LIS Subsidies
2006	45.5%	39.0%	15.6%	54.5%	36.5%
2007	42.2%	39.1%	18.7%	57.8%	41.2%
2008	39.2%	39.9%	20.9%	60.8%	39.4%
2009	38.9%	40.3%	20.8%	61.1%	38.9%
2010	38.0%	40.4%	21.6%	62.0%	19.0%
2011	35.7%	39.7%	24.6%	64.3%	31.8%
2012	35.4%	38.2%	26.4%	64.6%	37.2%

Source: 2013 Annual Report from the Medicare Trustees.

Exhibit 7
Spending on Specialty Tier Drugs
Medicare Part D: 2007
Little Beneficiary Specialty Drug Out-of-Pocket Exposure
($billions)

	LIS Beneficiaries	LIS Share of Spending	Non-LIS Beneficiaries	Non-LIS Share of Spending	Total Medicare Part D	Total Part D Share of Spending
Paid by Medicare	**$3.11**	**78.5%**	**$0.70**	**42.2%**	**$3.81**	**67.8%**
Paid by Plans	**0.84**	**21.2%**	**0.63**	**38.0%**	**1.47**	**26.2%**
Paid by Beneficiaries	**0.01**	**0.3%**	**0.33**	**19.9%**	**0.34**	**6.0%**
Total Specialty Drug Spending	**$3.96**	**100.0%**	**$1.66**	**100.0%**	**$5.62**	**100.0%**

Source: GAO-10-242, "Medicare Part D Specialty Tier-Eligible Drugs, January 2010

Exhibit 8

Manufacturer Defendant Part D "Financial" Assistance

Beneficiary (PAP) and Plan Sponsor "Support" Key to Enabling Pricing Fraud

($)

	2006	2013	Change 2006-13
Annual Part D MS Drug Cost ($)	**$15,000**	**$50,000**	**$35,000**
Annual *"Catastrophic"* Threshold	**$3,600**	**$4,750**	**$1,150**
MS Drug Cost above Threshold	**$11,400**	**$45,250**	**$33,850**
Financial Responsibility above Threshold			
CMS (80%)	**$9,120**	**$36,200**	**$27,080**
Plan Sponsor (15%)	**$1,710**	**$6,788**	**$5,078**
Beneficiary (5%)	**$570**	**$2,263**	**$1,693**
Non-LIS Beneficiary Financial Exposure	**$4,170**	**$7,013**	**$2,843**
Combined Non-LIS Beneficiary/Plan Sponsor Financial Exposure	**$5,880**	**$13,800**	**$7,920**
Manufacturer Revenues after Full PAP Support	**$10,830**	**$42,988**	**$32,158**
Full PAP as % of Annual Drug Cost (%)	**28%**	**14%**	**8%**
Manufacturer Revenues after Full PAP/Plan Sponsor Support	**$9,120**	**$36,200**	**$27,080**
Full PAP/Plan Sponsor Support as % of Annual Drug Cost (%)	**39%**	**28%**	**-**

Source: CMS, Corporate reports and numerous public pricing databases.

Exhibit 9

Medicare Part D Catastrophic Drug Spending

Fast Rising Drug Costs and Plan Sponsor Cost-Sharing Burden

($billions)

Aggregate Part D Program:

	Annual Reinsurance Subsidies	Annual Catastrophic Spending	Annual Plan Sponsor Cost-Sharing (15%)
2006	$6.0	$7.5	$1.1
2007	8.0	10.0	1.5
2008	9.4	11.8	1.8
2009	10.1	12.6	1.9
2010	11.2	14.0	2.1
2011	13.8	17.3	2.6
2012	15.6	19.6	2.9
Cumulative 2006-2012	**$74.3**	**$92.8**	**$13.9**

Source: 2013 Medicare Trustees Report.

Exhibit 10

Part D LIS Enrollment and Subsidies

2006 to 2012

Program Year	Total LIS Enrollment (millions)	State Full LIS Enrollment (millions)	State Full LIS % of LIS Enrollment	Annual Program LIS Subsidies ($bil)	State *"Clawback"* Transfers ($bil)	State *"Clawback"* % of Total LIS Subsidies
2006	8.3	5.7	68.7%	$15.1	$5.5	36.5%
2007	9.2	5.9	64.1%	$16.7	$6.9	41.2%
2008	9.7	6.3	64.9%	$18.0	$7.1	39.4%
2009	10.0	6.4	64.0%	$19.6	$7.6	38.9%
2010	10.4	6.6	63.5%	$21.0	$4.0	19.0%
2011	10.6	6.6	62.3%	$22.3	$7.1	31.8%
2012	11.0	6.9	62.7%	$22.6	$8.4	37.2%
Cumulative 2006-2013	-	-	-	$135.3	$46.6	-
Growth 2012 vs. 2006	33%	21%	-	50%	53%	

Source: 2013 Annual Report from the Medicare Trustees

Exhibit 11

Massive Medicaid/340B Discounts for Defendant MS Drugs

Pricing Data as of December 2013

		Annual Cost			Per Cent Medicaid/340B
	Dosage	AWP[1]	Medicaid/340B	Delta	Discount
Avonex (Biogen)	**30 mcg per week**	**$60,595.20**	**$3,119.40**	**$57,475.80**	**95%**
Copaxone (Teva)	**20mg per day**	**$66,304.68**	**$609.72**	**$65,694.96**	**99%**
Betaseron (Bayer)	**.25mg every other day**	**$53,192.16**	**$10,081.44**	**$43,110.72**	**81%**

[1] Average Wholesaler Price (AWP)

Source: Confidential Wholesaler Data

Exhibit 12

Top "Dual Eligible" States by Enrollment: 2008

	State	Total Medicare Beneficiaries	Number of Dual Eligibles	State Share of National Duals	Duals as % of Total Medicare	Full Duals as % of All Dual Eligibles	Under 65, Disabled Duals as % of All Duals
1	**California**	4,470,439	1,201,009	13.1%	26.9%	98.0%	35.0%
2	**New York**	2,877,270	737,161	8.1%	25.6%	89.0%	35.0%
3	**Texas**	2,778,533	626,375	6.9%	22.5%	61.0%	36.0%
4	**Florida**	3,180,256	601,276	6.6%	18.9%	58.0%	40.0%
5	**Pennsylvania**	2,210,989	391,855	4.3%	17.7%	85.0%	32.0%
6	**Illinois**	1,769,546	313,365	3.4%	17.7%	88.0%	44.0%
7	**North Carolina**	1,392,450	310,496	3.4%	22.3%	81.0%	44.0%
8	**Ohio**	1,830,807	303,761	3.3%	16.6%	68.0%	38.0%
9	**Tennessee**	995,254	284,368	3.1%	28.6%	76.0%	45.0%
10	**Michigan**	1,571,709	263,859	2.9%	16.8%	89.0%	41.0%
	Subtotal Top 10 States	**23,077,253**	**5,033,525**	**55.1%**	**21.8%**	-	-
11	**Georgia**	1,145,727	264,172	2.9%	23.1%	55.0%	40.0%
12	**Massachusetts**	1,015,086	254,979	2.8%	25.1%	97.0%	23.0%
13	**Alabama**	804,351	208,250	2.3%	25.9%	48.0%	43.0%
14	**Wisconsin**	871,111	211,378	2.3%	24.3%	61.0%	46.0%
15	**New Jersey**	1,279,020	203,908	2.2%	15.9%	84.0%	41.0%
16	**Kentucky**	724,356	178,381	2.0%	24.6%	62.0%	38.0%
17	**Louisiana**	653,018	180,354	2.0%	27.6%	59.0%	35.0%
	Rest of States	**29,569,922**	**6,534,947**	**71.5%**	**22.1%**	-	-
	Total United States	**44,106,250**	**9,142,653**	**100.0%**	**20.7%**	**77.0%**	**39.0%**

Source: Kaiser Family Foundation Issue Brief, "Medicare Role for Dual Eligible Beneficiaries, April 2012.

Exhibit 13

Medicare Part D "Dual Eligibles" by State: 2008

	State	Total Medicare Beneficiaries	Number of Dual Eligibles	State Share of National Duals	Duals as % of Total Medicare	Full Duals as % of All Dual Eligibles	Under 65, Disabled Duals as % of All Duals
1	Alabama	804,351	208,250	2.3%	25.9%	48.0%	43.0%
2	Alaska	59,435	13,006	0.1%	21.9%	98.0%	40.0%
3	Arizona	852,880	147,966	1.6%	17.3%	77.0%	43.0%
4	Arkansas	505,634	118,405	1.3%	23.4%	58.0%	39.0%
5	California	4,470,439	1,201,009	13.1%	26.9%	98.0%	35.0%
6	Colorado	574,263	69,872	0.8%	12.2%	92.0%	34.0%
7	Connecticut	546,623	103,162	1.1%	18.9%	76.0%	57.0%
8	Delaware	139,709	23,796	0.3%	17.0%	47.0%	46.0%
9	District of Columbia	74,805	22,192	0.2%	29.7%	85.0%	25.0%
10	Florida	3,180,256	601,276	6.6%	18.9%	58.0%	40.0%
11	Georgia	1,145,727	264,172	2.9%	23.1%	55.0%	40.0%
12	Hawaii	193,333	32,688	0.4%	16.9%	91.0%	39.0%
13	Idaho	212,381	30,889	0.3%	14.5%	70.0%	41.0%
14	Illinois	1,769,546	313,365	3.4%	17.7%	88.0%	44.0%
15	Indiana	958,270	155,826	1.7%	16.3%	65.0%	48.0%
16	Iowa	504,944	81,382	0.9%	16.1%	84.0%	52.0%
17	Kansas	416,167	63,077	0.7%	15.2%	74.0%	44.0%
18	Kentucky	724,356	178,381	2.0%	24.6%	62.0%	38.0%
19	Louisiana	653,018	180,354	2.0%	27.6%	59.0%	35.0%
20	Maine	252,025	91,976	1.0%	36.5%	58.0%	56.0%
21	Maryland	740,811	109,905	1.2%	14.8%	68.0%	34.0%
22	Massachusetts	1,015,086	254,979	2.8%	25.1%	97.0%	23.0%
23	Michigan	1,571,709	263,859	2.9%	16.8%	89.0%	41.0%
24	Minnesota	746,505	132,224	1.4%	17.7%	91.0%	49.0%
25	Mississippi	476,564	150,850	1.6%	31.7%	54.0%	39.0%
26	Missouri	961,308	171,506	1.9%	17.8%	91.0%	45.0%
27	Montana	159,650	18,446	0.2%	11.6%	86.0%	40.0%
28	Nebraska	270,435	41,643	0.5%	15.4%	90.0%	54.0%
29	Nevada	327,629	40,009	0.4%	12.2%	54.0%	40.0%
30	New Hampshire	203,608	28,783	0.3%	14.1%	71.0%	60.0%
31	New Jersey	1,279,020	203,908	2.2%	15.9%	84.0%	41.0%
32	New Mexico	292,363	55,971	0.6%	19.1%	71.0%	36.0%
33	New York	2,877,270	737,161	8.1%	25.6%	89.0%	35.0%
34	North Carolina	1,392,450	310,496	3.4%	22.3%	81.0%	44.0%
35	North Dakota	106,005	15,353	0.2%	14.5%	74.0%	57.0%
36	Ohio	1,830,807	303,761	3.3%	16.6%	68.0%	38.0%
37	Oklahoma	575,298	113,553	1.2%	19.7%	84.0%	45.0%
38	Oregon	580,425	90,355	1.0%	15.6%	69.0%	46.0%
39	Pennsylvania	2,210,989	391,855	4.3%	17.7%	85.0%	32.0%

40	**Rhode Island**	177,279	39,388	0.4%	22.2%	86.0%	39.0%
41	**South Carolina**	714,008	150,973	1.7%	21.1%	87.0%	46.0%
42	**South Dakota**	131,368	20,520	0.2%	15.6%	67.0%	48.0%
43	**Tennessee**	995,254	284,368	3.1%	28.6%	76.0%	45.0%
44	**Texas**	2,778,533	626,375	6.9%	22.5%	61.0%	36.0%
45	**Utah**	262,064	30,952	0.3%	11.8%	91.0%	44.0%
46	**Vermont**	104,460	31,828	0.3%	30.5%	63.0%	56.0%
47	**Virginia**	1,071,681	171,681	1.9%	16.0%	69.0%	45.0%
48	**Washington**	896,838	149,782	1.6%	16.7%	76.0%	37.0%
49	**West Virginia**	371,770	79,682	0.9%	21.4%	62.0%	35.0%
50	**Wisconsin**	871,111	211,378	2.3%	24.3%	61.0%	46.0%
51	**Wyoming**	75,790	10,065	0.1%	13.3%	68.0%	46.0%
	United States	**44,106,250**	**9,142,653**	**100.0%**	**20.7%**	**77.0%**	**39.0%**

Source: Kaiser Family Foundation Issue Brief, "Medicare Role for Dual Eligible Beneficiaries, April 2012.

Exhibit 14

Top Five Medicare Part D PDPs, 2013

By LIS and Non-LIS Enrollment

PDP Plan	Plan Sponsor	Plan PBM	Total LIS Enrollment	Share of US LIS Enrollees	LIS Share in Plan
SilverScript Basic	**CVS Caremark**	**CVS Caremark**	2,601,000	31.6%	86.0%
Humana Walmart Preferred Rx Plan	**Humana**	**Humana**	926,000	11.2%	52.8%
AARP Medicare Rx Preferred	**United Healthcare**	**United Healthcare**	737,000	8.9%	19.1%
Cigna MedicareRx Plan One	**Cigna**	**Cigna/Catamaran**	592,000	7.2%	86.4%
Wellcare Classic	**Wellcare**	**Wellcare**	436,000	5.3%	69.0%
Total Top 5 LIS PDPs	**-**	**-**	**5,292,000**	**64.2%**	-

PDP Plan	Plan Sponsor	Plan PBM	Total Non-LIS Enrollment	Share of US Non-LIS Enrollees	Non-LIS Share in Plan
AARP MedicareRx Preferred	**United Healthcare**	**United Healthcare**	3,114,000	31.9%	80.9%
Humana Enhanced	**Humana**	**Humana**	1,134,000	11.6%	86.3%
Humana Walmart-Preferred Rx Plan	**CVS Caremark**	**CVS Caremark**	829,000	8.5%	47.2%
First Health Part D-Value Plus[1]	**Coventry/Aetna**	**Aetna/Express Scripts**	617,000	6.3%	95.7%
SilverScript Basic	**CVS Caremark**	**CVS Caremark**	422,000	4.3%	14.0%
Total Top 5 Non-LIS PDPs	**-**	**-**	**6,116,000**	**62.6%**	-

1 Coventry was acquired by Aetna in May 2013.

Source: Medicare Part D Prescription Drug Plans, Kaiser Family Foundation, Issue Brief, December 2013

Exhibit 15

National Medicare Part D PDP and Medicare Advantage Enrollment, 2012

National Medicare PDP Enrollment, 2012

Plan Sponsor	*PBM*	*2012 Part D PDP Enrollment (000s)*	*% of 2012 PDP Enrollment*	*Number of Plans*	*% of PDP 2012 PDP Plans*
UnitedHealth Group, Inc.	**United Health Group**	4,231.5	21.1%	99	7.9%
CVS Caremark Corporation	**Caremark CVS**	4,009.4	20.0%	213	17.1%
Humana	**Humana**	2,998.0	14.9%	106	8.5%
Express Scripts	**Express Scripts**	1,689.7	8.4%	71	5.7%
Coventry Healthcare, Inc.	**Express Scripts**	1,577.3	7.9%	118	9.5%
Cigna	**Cigna/Catamaran**	1,268.7	6.3%	115	9.2%
WellCare Health Plans, Inc.	**WellCare**	874.3	4.4%	68	5.5%
Wellpoint, Inc.	**Wellpoint/Express Scripts**	535.8	2.7%	80	6.4%
Aetna, Inc.	**Aetna/CVS Caremark**	480.6	2.4%	69	5.5%
Envision Insurance Company	**Express Scripts**	383.6	1.9%	70	5.6%
All Others (53 organizations)	**Various**	2,018.6	10.1%	238	19.1%
Total		**20,066.9**	**100.0%**	**1,247**	**100.0%**

National Medicare Advantage Enrollment, 2012

Firm or Affiliate	*PBM*	*2012 MA Enrollment (000s)*	*% of 2012 MA Enrollment*
UnitedHealth Group, Inc.	**United Health Group**	2,552.2	19.5%
Humana	**Humana**	2,217.2	16.9%
Other BlueCross/BlueShield	**Express Scripts**	1,673.6	12.8%
Kaiser Permanente	**Kaiser**	1,073.6	8.2%
Wellpoint BlueCross/BlueShield	**Wellpoint/Express Scripts**	581.2	4.4%
Aetna, Inc.	**Aetna/CVS Caremark**	421.6	3.2%
Cigna	**Cigna/Catamaran**	399.8	3.1%
Coventry	**Express Scripts**	246.4	1.9%
HealthNet	**HealthNet**	240.1	1.8%
Wellcare	**WellCare**	147.8	1.1%
All Others	**Various**	3,536.2	27.0%
Total		**13,089.7**	**100.0%**

Source: Pembroke Consulting Analysis of CMS data and Kaiser Family Foundation, Medicare Advantage 2012 Data Spotlight: Enrollment Market Update.

Exhibit 16

PBM Share of Medicare Part D Marketplace: 2012

PDP and Medicare Advantage Markets

Extreme PBM Concentration Fuels Collusive Drug Pricing

PBM Share of PDP Market:	***2012 PDP Enrollment (000s)***	***% of 2012 PDP Enrollment***	***Top 3 PBMs Share***
			64.3%
CVS Caremark Corporation	**4,490.0**	**22.4%**	
UnitedHealth Group, Inc.	**4,231.5**	**21.1%**	***Top 4 PBMs***
Express Scripts Holding Company	**4,186.4**	**20.9%**	***Share***
Humana	**2,998.0**	**14.9%**	**79.3%**
Catamaran	**1,268.7**	**6.3%**	
WellCare	**874.3**	**4.4%**	***Top 6 PBMs***
All Other	**2,018.0**	**10.1%**	***Share***
Total	**20,066.9**	**100.0%**	**89.9%**

PBM Share of Medicare Advantage (MA) Market:	***2012 MA Enrollment (000s)***	***% of 2012 MA Enrollment***	***Top 3 PBMs Share***
			55.5%
UnitedHealth Group, Inc.	**2,552.2**	**19.5%**	
Express Scripts Holding Company	**2,501.2**	**19.1%**	***Top 4 PBMs***
Humana	**2,217.2**	**16.9%**	***Share***
CVS Caremark Corporation	**421.6**	**3.2%**	**58.8%**
Catamaran	**399.8**	**3.1%**	
WellCare	**147.8**	**1.1%**	***Top 6 PBMs***
All Other	**4,849.9**	**37.1%**	***Share***
Total	**13,089.7**	**100.0%**	**62.9%**

PBM Share of Combined PDP/MA Market:	***2012 PDP/MA Enrollment (000s)***	***% of 2012 PDP/MA Enrollment***	***Top 3 PBMs Share***
			56.4%
UnitedHealth Group, Inc.	**6,783.7**	**20.5%**	
Express Scripts Holding Company	**6,687.6**	**20.2%**	***Top 4 PBMs***
Humana	**5,215.2**	**15.7%**	***Share***
CVS Caremark Corporation	**4,911.6**	**14.8%**	**71.2%**
Catamaran	**1,668.5**	**5.0%**	
WellCare	**1,022.1**	**3.1%**	***Top 6 PBMs***
All Other	**6,867.9**	**20.7%**	***Share***
Total	**33,156.6**	**100.0%**	**79.3%**

Source: Pembroke Consulting Analysis of CMS data and Kaiser Family Foundation,

Medicare Advantage 2012 Data Spotlight: Enrollment Market Update.

Exhibit 17

Benefit Channel by Specialty Drug Category: 2010

	Benefit Handling	
Therapeutic Area	**Pharmacy**	**Medical**
Inflammatory Conditions	**68.2%**	**31.8%**
Cancer	**22.4%**	**77.6%**
Multiple Sclerosis	**90.4%**	**9.6%**
HIV	**99.9%**	**0.1%**
Other	**-**	**-**
Total Specialty Drug Spending	**52.9%**	**47.1%**

Source: Express Scripts 2011 Specialty Drug Report, page 9

Exhibit 18
US Specialty Drug Spending Trends: 2011-2013
Share of Spending Growth
Adjusted for Per cent via Pharmacy Benefit and Enrollment

	2011	2012	2013
Commercial Market			
Cancer	10.6%	8.8%	5.6%
Inflammatory Conditions	23.3%	39.3%	48.5%
Multiple Sclerosis	23.0%	27.2%	40.9%
Pulmonary Hypertension	-0.3%	6.2%	-2.9%
Anticoagulants	-4.1%	1.9%	-5.0%
Hepatitis C	28.0%	8.5%	-
Other	19.5%	7.9%	55.3%
Total Commercial Specialty	100.0%	100.0%	100.0%
Medicare			
Cancer	19.2%	17.4%	13.1%
Inflammatory Conditions	14.2%	17.3%	13.5%
Multiple Sclerosis	28.4%	44.4%	38.6%
Pulmonary Hypertension	6.4%	15.9%	1.9%
Anticoagulants	0.4%	7.8%	-
Hepatitis C	16.8%	7.9%	-
Other	14.5%	-10.7%	63.0%
Total Medicare Specialty	100.0%	100.0%	100.0%
Combined Commercial/Medicare			
Cancer	12.9%	11.5%	9.1%
Inflammatory Conditions	20.9%	32.5%	32.0%
Multiple Sclerosis	24.5%	32.6%	39.8%
HIV	-	-	-
Pulmonary Hypertension	1.5%	9.2%	-0.6%
Anticoagulants	-2.9%	3.8%	-11.1%
Hepatitis C	24.9%	8.3%	-
Other	18.1%	2.1%	58.9%
Total Combined Specialty	100.0%	100.0%	100.0%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2013.

Exhibit 19
US Specialty Part D Drug Spending Trends: 2010-2013
Share of Spending By Insurance Segment and Therapeutic Category
Adjusted for Per cent via Pharmacy Benefit

	2010	2011	2012	2013
Commercial Market (%)				
Cancer	5.3%	6.1%	6.5%	6.4%
Inflammatory Conditions	31.2%	30.0%	31.5%	33.9%
Multiple Sclerosis	33.7%	32.1%	31.3%	32.7%
Pulmonary Hypertension	4.0%	3.3%	3.8%	2.9%
Anticoagulants	8.4%	6.5%	5.8%	4.2%
Hepatitis C	3.0%	6.8%	7.1%	-
Other	9.1%	9.3%	8.2%	9.6%
Total Commercial Specialty	100.0%	100.0%	100.0%	100.0%
Medicare (%)				
Cancer	9.9%	11.7%	13.0%	13.0%
Inflammatory Conditions	18.2%	17.4%	17.4%	16.2%
Multiple Sclerosis	17.1%	19.2%	25.0%	29.3%
Pulmonary Hypertension	8.7%	8.3%	10.0%	7.4%
Anticoagulants	10.3%	8.4%	8.3%	-
Hepatitis C	2.4%	5.1%	5.7%	-
Other	33.5%	29.9%	20.6%	34.1%
Total Medicare Specialty	100.0%	100.0%	100.0%	100.0%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2013.

Exhibit 20

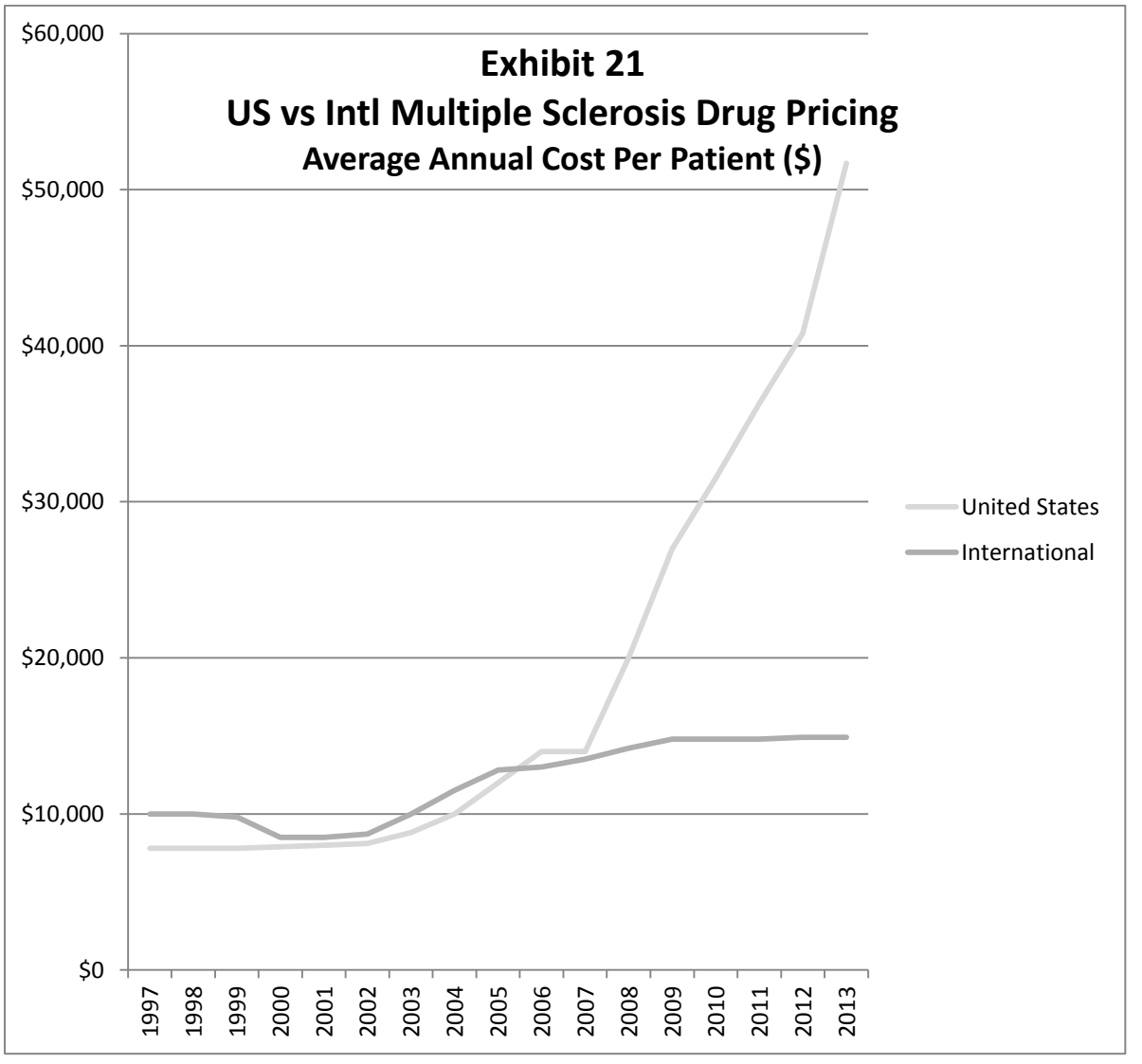
Express Scripts Medicare MS Drug Reported Trends: 2010-2013

Potential for Significant Under-Reporting of MS Price Inflation Impact

					Annual Growth		
	2010	**2011**	**2012**	**2013**	**2011**	**2013**	**2013**
Reported Growth Trends							
Cost	**11.4%**	**14.1%**	**18.2%**	**14.1%**	**-**	**-**	**-**
Utilization	**9.6%**	**20.3%**	**8.5%**	**5.7%**	**-**	**-**	**-**
Total Growth	**21.0%**	**34.4%**	**26.7%**	**19.8%**	**-**	**-**	**-**
Price Increases as % of Growth	**54.3%**	**41.0%**	**68.2%**	**71.2%**	**-**	**-**	**-**
Utilization as % of Growth	**45.7%**	**59.0%**	**31.8%**	**28.8%**	**-**	**-**	**-**
Medicare (PMPY Spend, $)[1]							
Multiple Sclerosis	**$24.00**	**$32.10**	**$51.68**	**$85.18**	**34%**	**61%**	**65%**

[1] PMPY = Per Member Per Year (in $)

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2013.



Source: Company Data, Price Rx, Credit Suisse estimates.

Exhibit 22
Medicare Part D Rebate Rate Trends: 2006-2022
(As % of Overall Program Spending)

2006	**8.6%**
2007	**9.6%**
2008	**10.4%**
2009	**11.1%**
2010	**11.3%**
2011	**11.5%**
2012	**11.1%**
2013E	**10.9%**
2014E	**10.9%**
2015E	**10.4%**
2016E	**10.2%**
2017E	**10.3%**
2018E	**10.3%**
2019E	**10.3%**
2020E	**10.3%**
2021E	**10.3%**
2022E	**10.3%**

Source: 2013 Annual Report from the Medicare Trustees.

Exhibit 23

US Specialty Drug Spending Trends: 2010-2013

By Insurance Segment and Therapeutic Category

Adjusted for Per cent via Pharmacy Benefit and Enrollment

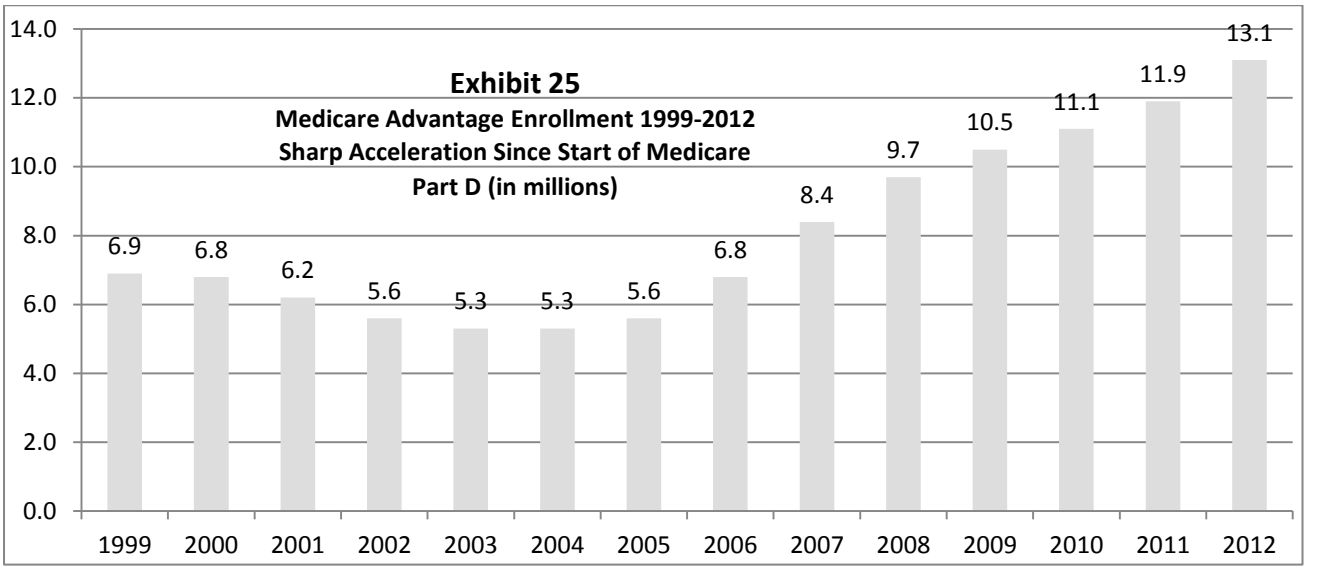
	2010	2011	2012	2013
Combined Commercial/Medicare ($ millions)				
Cancer	$1,253	$1,742	$2,330	$2,957
Inflammatory Conditions	5,625	6,414	8,076	10,279
Multiple Sclerosis	5,977	6,902	8,568	11,309
Pulmonary Hypertension	999	1,056	1,529	1,486
Anticoagulants	1,748	1,640	1,833	1,072
Hepatitis C	572	1,515	1,941	-
Other	3,695	4,381	4,490	8,545
Total Combined Specialty	$19,868	$23,650	$28,767	$35,648
Annual Growth Rate	-	19%	22%	24%
Medicare as % of Combined Spending				
Cancer	34.5%	36.1%	38.9%	45.0%
Inflammatory Conditions	14.1%	14.6%	15.0%	16.1%
Multiple Sclerosis	**12.5%**	**15.0%**	**20.3%**	**26.5%**
Pulmonary Hypertension	38.0%	42.2%	45.7%	51.2%
Anticoagulants	25.7%	27.7%	31.6%	-
Hepatitis C	18.0%	18.2%	20.6%	-
Other	39.5%	36.7%	32.0%	40.7%
Total Medicare Specialty	22.0%	22.8%	24.3%	28.7%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2013.

Exhibit 24
Example Service Fee Fair Market Value (FMV) Analysis
Patient Support Program

Cost-Build-up Method						Market Method			
Complexity	Duration (minutes)	Labor Price Per Hour Low	Labor Price Per Hour High	FMV Per Call Low	FMV Per Call High	Complexity	Observed Prices Low		Observed Prices High
Medium (Staff Nurse)	5 to 20	$X	$Y	$X	$Y	Medium	$a	to	$b
	21 to 30	$X	$Y	$X	$Y				
	31 to 40	$X	$Y	$X	$Y				
	41 to 50	$X	$Y	$X	$Y				
	51 to 60	$X	$Y	$X	$Y				
	52 to 60	$X	$Y	$X	$Y				
High (Pharmacist)	5 to 20	$X	$Y	$X	$Y	High	$a	to	$b
	21 to 30	$X	$Y	$X	$Y				
	31 to 40	$X	$Y	$X	$Y				
	41 to 50	$X	$Y	$X	$Y				
	51 to 60	$X	$Y	$X	$Y				
	52 to 60	$X	$Y	$X	$Y				

Source: Huron Life Sciences, Presentation 9/27/12.



Source: Kaiser Family Foundation.

Exhibit 26

Medicare Part D Pricing Across Plans and Geographies

Identical Pricing Suggests Near Complete Collusion

PlanPrescriber.com Search as of 9/3/2013

		Avg. Annual Part D Drug Cost			Avg. Monthly Part D Drug Cost		
	Dosage	New York	Minneapolis	Los Angeles	New York	Minneapolis	Los Angeles
Zip Code		11935	48322	91331	11935	48322	91331
Number of Medicare PDP Plans		25	26	27	25	26	27
Multiple Sclerosis							
Avonex (Biogen)	30 mcg per week	$46,851	$46,851	$46,851	$3,904	$3,904	$3,904
Copaxone (Teva)	20 mg per day	$49,904	$49,904	$49,904	$4,159	$4,159	$4,159
Rebif (Pfizer)	22 mcg three times a week	$41,567	$41,567	$41,567	$3,464	$3,464	$3,464
Rheumatoid Arthritis							
Enbrel (Amgen)	25 mg twice a week	$25,881	$25,881	$25,881	$2,157	$2,157	$2,157
Humira (Abbvie)	40 mg every two weeks	$25,637	$25,637	$25,637	$2,136	$2,136	$2,136
Cancer							
Gleevec (Novartis)	400 mg once a day	$72,783	$72,783	$72,783	$6,065	$6,065	$6,065
Sprycel (Bristol Myers)	100 mg once a day	$102,329	$102,329	$102,329	$8,527	$8,527	$8,527
Tasigna (Novartis)	300 mg twice a day	$102,300	$102,300	$102,300	$8,525	$8,525	$8,525
Hepatitis C							
Incivek (Vertex)	750 mg TID	-	-	-	$20,568	$20,568	$20,568
Victrelis (Merck)	800 mg TID	-	-	-	$5,599	$5,599	$5,599
Pegasys (Roche)	180 mcg per week	-	-	-	$3,368	$3,368	$3,368
PegIntron (Merck)	80 mcg per week	-	-	-	$3,168	$3,168	$3,168
Diabetes							
Victoza (Novo Nordisk)	0.6 mg QD	$3,810	$3,810	$3,810	$318	$318	$318
Bydureon (Bristol Myers)	2 mg per week	$4,315	$4,315	$4,315	$360	$360	$360
Januvia (Merck)	25mg QD	$2,817	$2,817	$2,817	$235	$235	$235
Onglyza (BMY/AZN)	2.5 mg QD	$2,816	$2,816	$2,816	$235	$235	$235
Tradjenta (BI)	5 mg QD	$2,806	$2,806	$2,806	$234	$234	$234

Source: Ehealth, PlanPrescriber.com.

Exhibit 27
Breakdown of Los Angeles Part D PDP Plans
Highly Concentrated PBM Shares
PlanPrescriber.com Search as of 9/3/2013

PBM	Number of Plans	Share of Plans
Express Scripts	12	44.4%
CVS Caremark	5	18.5%
United Healthcare	3	11.1%
Humana	3	11.1%
Wellcare	2	7.4%
Catamaran	2	7.4%
Total Plans	27	100.0%

Source: Ehealth, PlanPrescriber.com.

Exhibit 28

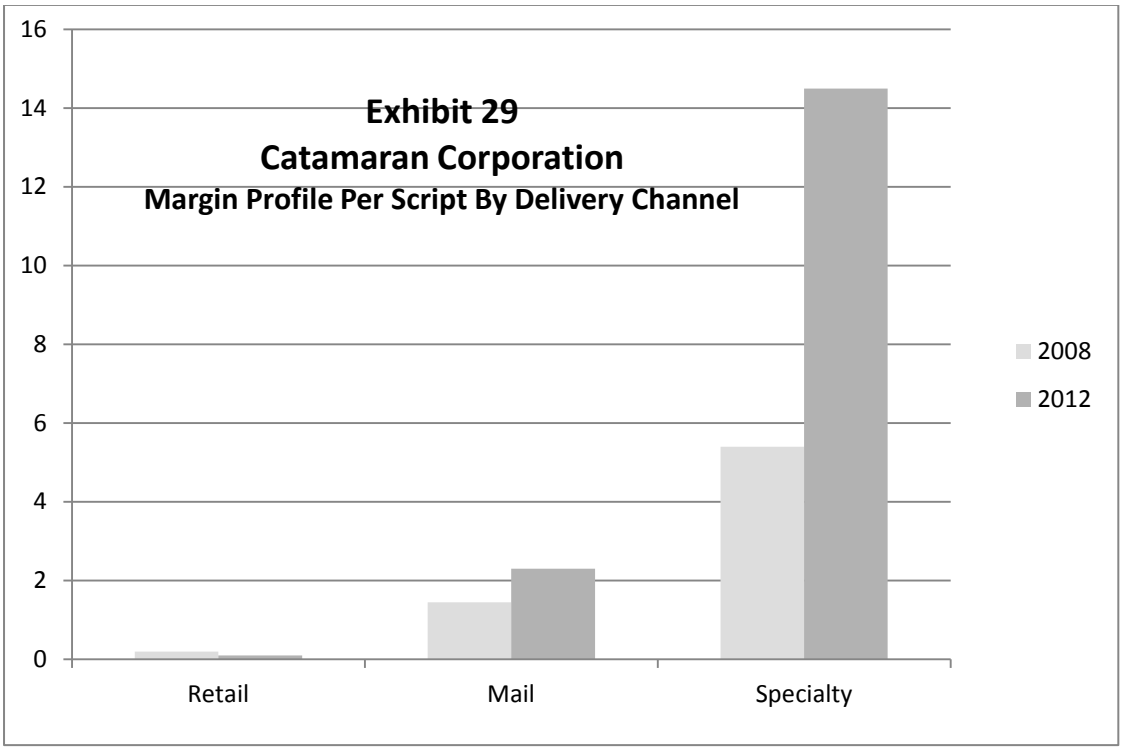
Comparison of Los Angeles Medicare Part D PDP Plans - Zip Code 91331

Identical Pricing for Defendant MS Drugs Across All Part D Plans

PlanPrescriber.com Search as of 9/3/2013

			Average Annual Part D Drug Cost by Plan ($)				
Plan	Sponsor	PBM	Avonex	Copaxone	Rebif	Enbrel	Gleevec
1) Blue Cross MedicareRx Plus	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
2 Blue Cross MedicareRx Gold	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
3) United American - Enhanced	United American	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
4) Express Scripts Medicare - Value	Express Scripts	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
5) Express Scripts Medicare - Choice	Express Scripts	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
6) Wellcare Classic	Wellcare	Wellcare	$46,851	$49,904	$41,567	$25,881	$72,783
7) Humana Walmart-Preferred Rx	Humana	Humana	$46,851	$49,904	$41,567	$25,881	$72,783
8) AARP Medicare Rx Saver Plus	United Healthcare	United Healthcare	$46,851	$49,904	$41,567	$25,881	$72,783
9) Wellcare Extra	Wellcare	Wellcare	$46,851	$49,904	$41,567	$25,881	$72,783
10) Human Enhanced	Humana	Humana	$46,851	$49,904	$41,567	$25,881	$72,783
11) Reader's Digest Value Rx	HealthMarkets	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
12) Aetna CVS PDP	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
13) Blue Cross MedicareRx Standard	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
14) AARP Medicare Rx Saver Preferred	United Healthcare	United Healthcare	$46,851	$49,904	$41,567	$25,881	$72,783
15) Cigna Medicare Rx Plan One	Cigna	Catamaran	$46,851	$49,904	$41,567	$25,881	$72,783
16) AARP Medicare Rx Enhanced	United Healthcare	United Healthcare	$46,851	$49,904	$41,567	$25,881	$72,783
17) Humana Complete	Humana	Humana	$46,851	$49,904	$41,567	$25,881	$72,783
18) Aetna Medicare Rx Premier	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
19) Blue Shield Medicare Basic Plan	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
20) Blue Shield Medicare Enhanced	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
21) United American Select	United American	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
22) EnvisionRxPlus Silver	Envision Insurance	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
23) EnvisionRxPlus Gold	Envision Insurance	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
24) HealthSpring PDP	Cigna	Catamaran	$46,851	$49,904	$41,567	$25,881	$72,783
25) First Health Part D Value Plus	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
26) First Health Part D Value Plus	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
27) First Health Part D Value Plus	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783

Source: Ehealth, PlanPrescriber.com.



Source: Slide from Catamaran Analyst Day Presentation slide, 11/15/12.

Exhibit 30

High Concentration in the US PBM Industry

($billion for 2013 Projected Revenues)

Company	***Sales***	***Share of US Market***
Express Scripts	**$96**	**27%**
Caremark CVS	**75**	**21%**
Optum Rx[1]	**34**	**10%**
Prime	**15**	**4%**
Catamaran	**14**	**4%**
Humana	**13**	**4%**
MedImpact	**8**	**2%**
Cigna	**8**	**2%**
All Others	**24**	**7%**
Total US PBM Sales	**$287**	**82%**
Total US Pharmaceutical Market	**$350**	**100%**

[1] Part of United Healthcare

Source: IMS Health and CVS Investor Day Presentation dated 12/13/12, slide 18.

Exhibit 31

High Concentration in the US Specialty Pharmacy Industry

Negotiating Leverage for Specialty Drugs Should be Extreme
($billion for 2013 Projected Revenues)

Company	***Sales ($bills)***	***Share of US Market***
Express Scripts	**$14.0**	**30%**
Caremark CVS	**$10.7**	**23%**
Walgreens	**$4.7**	**10%**
Diplomat Specialty	**$0.9**	**2%**
Omnicare	**$0.9**	**2%**
Other	**$15.4**	**33%**
Total US Specialty Sales	**$46.6**	**100%**

Source: Pembroke Consulting, June 2012.

Exhibit 32

US Medicaid Drug Spending

Inflation Rebates Negate Price Inflation

	Enrollees (millions)	Enrollment Growth	Gross Drug Spending ($bill)	Rebates ($bill)	Rebates as a % of Spending	Net Drug Spending ($bill)	Net Drug Spending per Enrollee ($)	Net Drug Spending Growth per Enrollee ($)
2006	59.9	-	$22.5	$8.6	38%	$13.9	$231.94	-
2007	59.4	-1%	22.6	6.6	29%	16.0	269.29	16%
2008	60.9	2%	24.0	8.0	33%	16.0	262.87	-2%
2009	64.5	6%	25.6	9.0	35%	16.6	257.27	-2%

Source: OIG HHS report; OEI-10-00320; August 2011.

Exhibit 33

Medicare Part D 2008 Rebate Data

Minimal PBM Retained Rebates

Vast Majority of PBM compensation via BFSFs

Total 2008 Medicare Part D Spending	**$63 billion**
Total Part D Sponsor Manufacturer Rebates	**$6.5 billion**
Manufacturer Rebates Retained by PBMs	**$24 million**
Rebates as % of 2008 Part D Spending	**10.3%**
Rebates as % of All Price Concessions	**98.0%**
PBM Retained Rebates as % of Overall	**0.4%**

Memo:

Sponsors reporting no rebates for themselves	**17.0%**
Sponsors Reporting no rebates retained by PBM	**61.0%**

Source: OIG Report, "Concerns with Rebates in the Medicare Part D Program", March 2011, OEI-02-08-00050.

Exhibit 34

Medicare Part D Specialty Drug Data: 2006-2008

Data for GAO Specialty Drug Report Dated January 2010

Price Concessions Negotiated by Seven Plan Sponsors[1]

For 20 Key Specialty Drugs

	Sponsors with Any Price Discounts			Annual Cost of Therapy After Price Concessions			Change 2006-	Annual Price Increase		Negotiated % Discount		
Drug/Manufacturer	2006	2007	2008	2006	2007	2008	2008	2007	2008	2006	2007	2008
Multiple Sclerosis												
Avonex (Biogen)	3	4	5	$16,764	$18,528	$22,608	35%	12%	23%	1.1%	2.2%	2.6%
Copaxone (Teva)	6	6	7	16,440	18,264	20,784	26%	13%	13%	6.2%	8.0%	7.2%
Inflammatory Conditions												
Humira (Abbvie)	6	7	7	$16,116	$16,896	$17,628	9%	6%	5%	6.1%	7.2%	8.2%
Enbrel (Amgen)	6	7	6	16,464	17,052	17,640	7%	4%	5%	2.0%	2.7%	3.7%
Anakinra (Amgen)	-	-	-	15,588	16,356	17,076	10%	5%	4%	0.0%	0.1%	0.1%
HIV												
Reyataz	5	6	6	$9,096	$9,384	$9,720	7%	4%	5%	2.7%	3.3%	5.0%
Truvada	0	0	0	9,180	9,780	10,572	15%	7%	8%	0.0%	0.0%	0.0%
Combivir	7	7	6	7,728	8,220	8,568	11%	6%	5%	3.3%	3.4%	3.6%
Kaletra	0	0	0	8,364	8,640	8,940	7%	3%	3%	0.0%	0.0%	0.0%
Cancer												
Tarceva (OSI/Roche)	0	0	0	$32,952	$37,236	$40,716	24%	13%	9%	0.0%	0.0%	0.0%
Gleevec (Novartis)	0	0	0	35,928	37,836	40,668	13%	5%	7%	0.0%	0.0%	0.0%
Pulmonary Hypertension												
Letairis (Gilead)	0	0	0	-	$49,200	$52,992	-	-	8%	-	0.0%	0.0%
Tracleer	0	0	0	41,796	48,780	53,076	27%	17%	9%	0.0%	0.0%	0.0%

[1] These Seven Sponsors accounted for 67% of Part D enrollment

Source: GAO-10-242, January 2010.

Exhibit 35

Medicare Part D Beneficiary Cost-sharing: 2012

Type of Beneficiary	Deductible	Initial Coverage Phase	Coverage Gap	Catastrophic
Full Low Income (LIS) Subsidy	$0	$1.10-2.60/generic; $3.30-6.50/branded	$1.10-2.60/generic; $3.30-6.50/branded	$0
Partial (LIS) Subsidy	$65	15%	15%	$2.60/generic; $6.50/branded
Non-LIS	$320	25% between $320 and $2,930	Next $3,800; 50% Beneficiary/50% Manufacturer discount for branded drugs; Beneficiary covers 86% for generic drugs	Above $6,730 ($4,700 beneficiary OOP Limit); 80% CMS/15% plan/5% beneficiary

Source: CMS.

Exhibit 36

Medicare Part D Prescription Drug Event (PDE) Cost Data

Key Fields Implicated in Service Fee Fraud

Field #	Data Element	Field Description	Service Fee Fraud Impact
26	**Catastrophic Coverage Code**	This field indicates that a beneficiary has reached the out-of-pocket threshold or attachment point. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing.	Escalating Reinsurance Subsidies due to both earlier and greater number of non-LIS beneficiaries exceeding Out-Of-Pocket annual limits; After threshold, CMS covers 80%, plan sponsor 15% and non-LIS beneficiary 5%; potential for significant fraud in handling of PBM Defendant 15% cost-sharing portion.
27	**Ingredient Cost Paid**	This field indicates that a beneficiary has reached the out-of-pocket threshold or attachment point. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing.	Fraudulently escalated end-user drug price due to service fee fraud; field only includes end-user price, not price paid by PBM and/or plan sponsor from manufacturer.
30	**Gross Drug Cost Below Out-of-Pocket Threshold (GDCB)**	This field represents the gross drug cost paid to the pharmacy below the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a positive dollar amount. For claims above the attachment point, the field will contain a zero dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 31 (GDCA).	Due to fraudulent price increases, non-LIS beneficiaries pay greater Out-Of-Pocket amounts and reach the Catastrophic level sooner and more frequently.
31	**Gross Drug Cost Above Out-of-Pocket Threshold (GDCA)**	This field represents the gross drug cost paid to the pharmacy above the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a zero dollar amount. For claims above the attachment point, the field will contain a positive dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 30 (GDCB).	Fraudulently escalated end-user drug prices increased the Catastrophic cost burden on both CMS and non-LIS beneficiaries; fraudulently elevated plan bids, Reinsurance Subsidies and catastrophic reconciliation payments.

Exhibit 36 (Continued)

Medicare Part D Prescription Drug Event (PDE) Cost Data

Key Fields Implicated in Service Fee Fraud

Field #	Data Element	Field Description	Service Fee Fraud Impact
32	**Patient Pay Amount**	This field lists the dollar amount the beneficiary paid that is not reimbursed by a third party (e.g., copayments, coinsurance, deductible or other patient pay amounts). This amount contributes to a beneficiary's TrOOP only when it is a payment for a covered drug. Payments made by the beneficiary or family and friends shall also be reported in this field. Other third party payments made on behalf of a beneficiary that contribute to TrOOP shall be reported in field 33 (Other TrOOP Amount) or field 34 (Low-Income Cost-Sharing Amount, LICS) and payments that do not contribute shall be reported in field 35 (Patient Liability Reduction due to Other Payer Amount.	Fraudulently high drug prices lead to increased Out-Of-Pocket costs for non-LIS and partial LIS beneficiaries, especially given typical 25-30% co-insurance requirements for many specialty drugs; greatly increased need for manufacturer-funded and independent Patient Assistance Programs (PAPs).
33	**Other True Out-of-Pocket (TrOOP) Amount**	This field records all qualified third party payments that contribute to a beneficiary's TrOOP, except for the Low-Income Cost Sharing (LICS) and Patient Pay Amount. Examples include payments made on behalf of a beneficiary by a qualified State Pharmacy Assistance Program, charities or other TrOOP-eligible parties.	Massive escalation in Other TrOOP Amounts from manufacturer-funded PAPs for non-LIS beneficiaries; potential path of fraudulent payments from manufacturers to PBMs via TrOOP administration.
34	**Low-Income Cost-Sharing Subsidy Amount (LICS)**	This field contains plan-reported LICS amounts per drug event so that CMS systems can reconcile prospective LICS payments made to plans with actual LICS amounts incurred by the plan at the Point of Sale.	The fee fraud and associated massive drug price inflation leads to fraudulent Direct, LIS Subsidy and reconciliation payments to plan sponsors for LIS beneficiaries, as well as fraudulent annual Subsidy estimates in plan bids.
35	**Patient Liability Reduction due to Other Payer Amount (PLPRO)**	This field takes into account coordination of benefits that result I reduced patient liability, excluding TrOOP-eligible payers; examples include group health plans, Worker's Compensation and government programs (e.g., VA, Tricare).	Potential fraudulent overpayment by other payers helping to pay for the fraudulent excessive drug costs due to fee fraud.
36	**Covered D Plan Paid Amount (CPP)**	This field contains the net amount the plan paid for standard benefits (covered Part d drugs).	Standard costs of all Part D plans escalated by the excessive Manufacturer Defendant drug costs.

Source: CMS.

Exhibit 37
State Clawback Phase-Down Rates

Plan Year	Rate
2006	**90.00%**
2007	**88.33%**
2008	**86.67%**
2009	**85.00%**
2010	**83.33%**
2011	**81.67%**
2012	**80.00%**
2013	**78.33%**
2014	**76.67%**
2015 and Beyond	**75.00%**

Source: CMS.

Exhibit 38

State Drug Spending Trends: 2006-2011

All State Increases Due to Part D Clawback Payments

	2006	2011	Change 2006-2011
Federal Medicaid	$10.8	$10.8	0%
State Medicaid	8.1	8.2	1%
Total Medicaid Drug Spending ($bil)	$18.9	$19.0	0%
Medicaid Enrollment (mil)	38.4	45.1	17%
Spending/Medicaid Enrollee ($)	$493	$420	-15%
State Part D Clawback Payments ($bil)	$5.5	$7.1	29%

Source: CMS, National Health Expenditures (NHE).

Exhibit 39

Comparison of Approved US Relapsing MS Treatments

	Avonex	Copaxone	Rebif	Betaseron/Extavia
Company/Yr of US Launch:	Biogen (1996)	Teva (1996)	Serono/Pfizer (2002)	Bayer (1993)/Novartis (2009)
Molecule Name:	Interferon beta -1a	Glatiramer acetate	Interferon beta -1a	Interferon beta -1b
Dosage:	30 micrograms once a week	20 mg day or 40 mg 3 times a week	22 or 44 mcg 3 times a week	0.25mg every other day
Mode of Delivery	Intramuscular injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection
FDA-Approved Indication:	Treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations.	For the treatment of patients with relapsing forms of multiple sclerosis.	For the treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability.	For the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.
Clinical Outcome Data:				
Disability:	At 2 years, 22% of Avonex patients and 35% of placebo patients had progression of disability (as measured by EDSS)[1;a] a 37% reduction in the risk of accumulating disability for Avonex patients.	Study 1: At 2 years, 80% of Copaxone patients were progression-free vs. 50% for placebo patients; Study 2: At 2 years, 78% of Copaxone patients progression-free vs. 75% for placebo patients; no disability data for 40mg dose.	At 2 years, 29% and 26% of 22mcg and 44mcg Rebif patients, respectively, had disability progression[4] vs. 37% for placebo patients.	At 2 year, 0.25mg dose Betaseron patients had a -0.07 change in their EDSS score vs. a +0.21 change for placebo patients.
MS Exacerbations:	At 2 years, 38% of Avonex patients were exacerbation-free compared to 26% of placebo patients; Annual exacerbation rate of 0.67 for Avonex patients compared to 0.82 for placebo patients.	Study 1: At 2 years, 56% of Copaxone patients were relapse-free vs. 28% of placebo patients; Study 2: At 2 years, 34% of Copaxone patients were relapse-free vs. 27% for placebo patients; 40mg study: 34% reduction in exacerbations for Copaxone patients at 1 year.	At 2 years, 29% and 32% decrease in exacerbations for 22mcg and 44mcg Rebif patients, respectively, vs. placebo patients; 25% and 32% of 22mcg and 44mcg Rebif patients, respectively, exacerbation-free at years vs. 15% for placebo patients.	At 2 year, 25% of 0.25mg dose Betaseron patients were exacerbation-free vs. 16% for placebo patients.
MRI[2] brain lesions:	At 1 year, the number of MRI lesions decreased by 13.1% for Avonex patients compared to a 3.3% decrease for placebo patients. At 2 years, the change was -13.2% for Avonex patients and -6.5% for placebo patients.	Study 4: Over 9 months, 11 cumulative Gd-enhancing lesions for Copaxone patient vs. 17 for placebo patients; 40mg study: 45% decrease in enhancing lesions for Copaxone patients at months 6 and 12.	At 2 year, the number of MRI lesions decreased by 1.2% and 3.8% for 22mcg and 44mcg Rebif patients vs. an 11% increase for placebo patients.	At 2 year, 0.25mg dose Betaseron patients had a -0.9% change in mean MRI lesions vs. +21.4% for placebo patients.
FDA-Approved Head-to-Head Clinical Data vs. Other MS Drugs:	None	None	62% of 44mcg-treated Rebif patients were relapse-free at 48 weeks vs. 52% for Avonex, representing a 19% decrease; at 24 weeks, 44mc-treated Rebif patients had 0.17 unique MRI lesions vs. 0.33 for Avonex.	None
Positives:	Convenient weekly dosing; long clinical experience; considered best tolerated inteferon; Biogen has new twice monthly version of Avonex (Pledigry) pending at the FDA.	Subcutaneous dosing; long clinical experience; skin side effects typically transient and self-limiting; viewed as well-tolerated by MDs; increased convenience of ne 40mg 3 times weekly version.	Subcutaneous interferon; high-dose (44mcg) has modest data suggesting clinical superiority over Avonex; long clinical experience.	Subcutaneous interferon; long clinical experience.
Negatives:	Intramuscular injection; interferon side effects; medical perception of lower efficacy vs. other interferons.	Required daily injection prior to early 2014 approval of 40mg 3 times weekly dose; Teva aggressively switching patients to new formulation ahead of potential 20mg dose generic competition in mid-2014.	Increased side effects, especially at high dose.	Less convenient dosing vs. Avonex; lacks Rebif's efficacy advantage.

Exhibit 39 (Continued)

Comparison of Approved US Relapsing MS Treatments

	Gilenya	Aubagio	Tecfidara
Company/Yr of US Launch:	Novartis (2010)	Sanofi (2012)	Biogen (2013)
Molecule Name:	fingolimod	teriflunomide	COPAXONE
Dosage:	0.5mg once a day	7mg or 14 mg once daily	240 mg twice a day
Mode of Delivery	Oral	Oral	Oral
FDA-Approved Indication:	For the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.	For the treatment of patients with relapsing forms of multiple sclerosis.	For the treatment of patients with relapsing forms of multiple sclerosis.
Clinical Outcome Data:			
Disability:	At 2 years, 18% of Gilenya patients and 24% of placebo patients had confirmed disability progression.	At 2 years, 21.7% and 20.2% of 7mg and 14mg Aubagio patients, respectively, had disability progression vs. 27.3% for placebo patients.	At 2 years, 16% of Tecfidara patients and 27% of placebo patients had progression of disability, a 38% relative risk reduction.
MS Exacerbations:	At 2 years, 70% of Gilenya patients were relapse-free compared to 46% of placebo patients; Annualized relapse rate of 0.18 for Gilenya-treated patients vs. 0.40 for placebo patients.	At 2 years, 53.7% and 56.5% of 7mg and 14mg Aubagio patients, respectively, were relapse-free vs. 45.6% for placebo patients; Annualized relapse rate of 0.370 and 0.368 for 7mg and 14mg Aubagio patients, respectively, vs. 0.539 for placebo patients.	At 2 years, 27% of Tecfidara patients relapsed compared to 46% of placebo patients, a 49% relative risk reduction; Annualized relapse rate of 0.172 for Tecfidara-treated patients vs. 0.364 for placebo patients.
MRI[2] brain lesions:	At 2 year, the mean number of Gd-enhancing lesions was 0.2 for Gilenya patients vs. 1.1 for placebo patients.	At 2 year, total MRI lesion volume increased by 0.755 and 0.345 for 7mg and 14mg Aubagio patients, respectively, vs. 1.127 for placebo patients.	At 2 year, 45% of Tecfidara patients had no new MRI lesions vs. 27% for placebo patients; At 2 years, the mean number of new MRI lesions was 2.6 for Tecfidara patients and 17 for placebo patients.
FDA-Approved Head-to-Head Clinical Data vs. Other MS Drugs:	At 1 year, 83% of Gilenya patients without relapse compared to 70% with Avonex patients; at 1 year, 1.6 new or enlarged MRI lesions for Gilenya patients vs. 2.6 for Avonex patients.	None	None
Positives:	Convenient oral dosing; highly-effective and well-tolerate once past early safety and monitoring issues.	Convenient oral dosing.	Strong efficacy, well-tolerated and convenient oral dosing; rapid uptake since spring 2013 US launch.
Negatives:	Risk of early cardiac toxicity, monitoring cumbersome to MDs.	Less efficacy vs other oral MS drugs; Black box warning, gastrointestinal tolerability	Approximately 20% patient discontinuation rate due to flushing and gastrointestinal tolerability issues.

1 EDSS (Kurtzke Expanded Disability Status Scale) - a scale that quantifies disability in patients with MS and ranges from 0 (normal neurologic exam) to 10 (death due to MS); for virtually all MS drug trials, progression of disability defined as an increase of 1 point in the EDSS scale.

2 Gadolinium (Gd)-Enhanced lesions seen on brain magnetic resonance imaging (MRI) scans represents areas of breakdown of the blood brain barrier thought to be secondary to inflammation (i.e., due to MS in these patients).

Source: FDA approved Prescribing Information labels for each drug.

Exhibit 40

"First Ever" Fair Market Value of Bona Fide Service Fees Conference

October 7-8, 2013, Philadelphia, PA

Presenter/Attendee List

Name	Title	Phone
Presenters (in chronological order)		
Tom Evegan	Senior Director, Commercial Contracting at Compliance Implementation Systems (CIS)	484-445-7200
John Shakow	Partner, King & Spalding	202-626-5523
Mark Linver[1]	Managing Director, Huron Consulting Group	312-583-8700
Stephanie Gilson	Assistant General Counsel, Johnson & Johnson	732-524-0400
Christopher Jackson	Corporate Attorney, Otsuka American Pharmaceuticals, Inc.	609-249-7292
Donna White	Senior Director, Contracts and Compliance at Cornerstone Therapeutics	609-409-7050
Joseph Metro	Partner, Reed Smith LLP	202-414-9284
Mark Dewyngaert, Ph.D.	Managing Director, Huron Consulting Group	312-583-8700
Michael Hepburn[2]	Senior Director, Government Contract Compliance at Janssen Pharmaceuticals, Inc.	908-927-2415
Doris Chern[2]	Senior Manager, Pricing Strategy and FMV at Janssen Pharmaceuticals, Inc.	908-927-2416
Jim Abrams	Director, Government Pricing and Reporting at Mylan Pharmaceuticals	304-598-5430
Trevor L. Wear	Senior Associate, Sidley Austin, LLP	312-853-7101
Julie DeLong, CFA	Director, Valuation and Financial Risk Management at Navigant Consulting, Inc.	404-602-5021
Isabel P. Dunst	Partner, Hogan Lovells US LLP	202-637-5818
John Moose, MBA, CPA, ABV	Project Leader, Huron Consulting Group	312-583-8700
Other Attendees		
Sajid Saeed	Director Fee-for-Service, GlaxoSmithKline	202-715-1048
Greg Haverkamp	Senior Manager of Government Contracts and Compliance, Novo Nordisk	609-987-5800
Mitzi Cole	Strategic Pharmaceutical/Biotechnology Legal Counsel, Pfizer	484-865-8779
Cynthia Bass	Associate General Counsel, Sanofi US	908-981-5000
Cheryl Allen	VP Development/Industry Relations, Diplomat Specialty Pharmacy	877-977-9118
Allyson Behm	Senior Corporate Attorney - Regulatory, Astellas	800-888-7704
Jason Carter	Senior Manager, Government Analytics & Compliance, Roche/Genentech	650-225-1000
Josh Parker	Director, Product Marketing, Express Scripts/Accredo Health	314-810-3123
Lyndsay Nahf	Director, Central Consultancy Group, Abbvie	847-932-7900

Exhibit 40 (Continued)

Linda Ozark	STAR Project Manager, Marketing Operations Systems, Abbvie	847-932-7900
Jill Thompson	Senior Counsel and Assistant Secretary, NPSP Pharmaceuticals	908-450-5300
John Walsh	Director Trade Account Management, Pfizer	212-733-2323
Christine Morse	Senior Attorney, Novo Nordisk	609-987-5800
Jamie Rowe	Senior Category Manager, Amgen	805-447-1000

[1] Mark Linver did not attend the conference; his presentation was given by his colleague, Mark Dewyngaert

[2] Janssen Pharmaceuticals is a division of Johnson & Johnson

Source: CBI conference agenda and attendee poster from conference, Corporate websites.

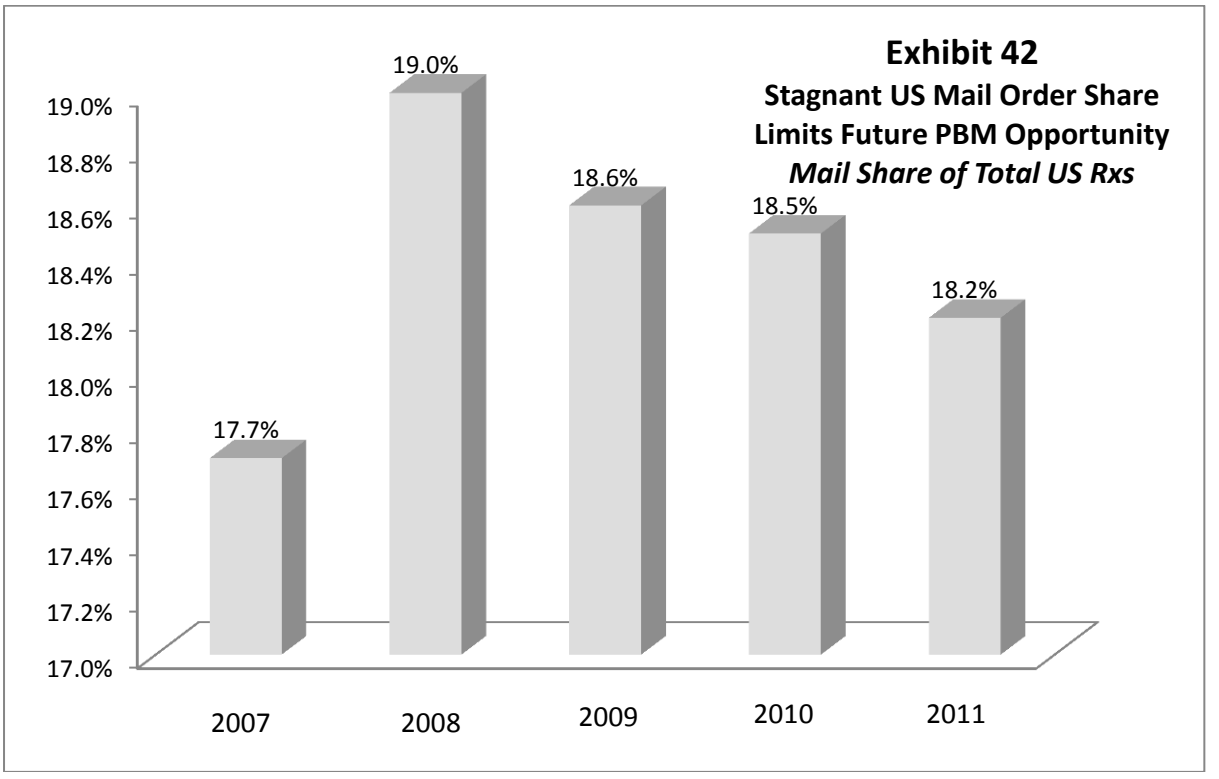
Exhibit 41

US Pharmaceutical Market

Traditional Slowdown Masking Specialty Drug Price Inflation

	2006	2007	2008	2009	2010	2011	2012
Total Prescription Market Share 1							
Generics	56%	60%	65%	69%	70%	74%	78%
Brands	44%	40%	35%	31%	30%	26%	22%
Total Traditional Market	100%	100%	100%	100%	100%	100%	100%
Total Prescription Growth							
Generics	-	6%	7%	7%	6%	4%	8%
Brands	-	-10%	-14%	-5%	-12%	-10%	-22%
Total Traditional Market	-	2%	0%	3%	2%	0%	2%
Total US Sales Growth 2							
Traditional Market	6%	5%	2%	5%	1%	0%	-2%
Specialty Drugs	21%	14%	15%	20%	20%	17%	18%
Total US Market	7%	6%	3%	6%	4%	3%	3%

Source: 1) IMS; 2) Express Scripts Drug Trends Reports, 2006-2012.



Source: IMS Health and CVS Investor Day Presentation dated 12/13/12, slide 18.

Exhibit 43
Merck/Medco Merger
Quick Benefit in Protecting Key Branded Drugs
Combined Retail and Mail Order Prescriptions
Market Share as Per Cent of New Prescriptions

	Therapeutic Category Market Share				Yr/Yr New Rx Growth	
Products	Nov 1992	Nov 1993	March 1994	April 1994	Nov 1993	Mar 1994
Vasotec	35.3%	32.1%	31.3%	31.1%	4.2%	4.0%
Vasoretic	3.3	3.0	3.0	3.0	3.3	4.8
Prinivil	8.8	7.8	10.0	9.7	1.3	35.0
Prinzide	1.6	1.4	1.6	1.7	2.4	23.2
All Merck ACE Inhibitors	49.0	44.4	45.9	45.4	3.6	10.1
Entire ACE Inhibitor Market	-	-	-	-	14.4	14.0
Mevacor	41.0%	34.6%	33.9%	33.3%	0.2%	3.1%
Zocor	8.3	13.1	14.7	14.9	86.8	79.7
All Merck Cholesterol - Lowering	49.3	47.6	48.6	48.3	14.8	18.3
All HMG-CoA Agents	61.0	65.6	67.0	66.7	27.7	22.6
Entire Cholesterol-Lowering Mkt	-	-	-	-	18.8	11.9

Source: IMS Health.

Exhibit 44
Specialty Drugs: Main Growth Driver of US Pharmaceutical Market
($billions)

				Avg Growth	
	2004	2011	2015E	2004-2011	2011-2015E
Traditional Pharmaceuticals	$197	$240	$253	3%	1%
Specialty Drugs	42	80	116	10%	10%
Total Market	$239	$320	$369	4%	4%
Share of US Market					
Traditional Pharmaceuticals	82.4%	75.0%	68.6%		
Specialty Drugs	17.6%	25.0%	31.4%		
Total Market	100.0%	100.0%	100.0%		
Contribution to Overall Growth					
Traditional Pharmaceuticals	-	53.1%	26.5%		
Specialty Drugs	-	46.9%	73.5%		
Total Market	-	100.0%	100.0%		

Source: IMS, Catamaran Investor Slide, 11/15/12; Health Strategies Group.

Exhibit 45
US Specialty Drug Market
High Growth Primarily Driven by Price Increases on Older Drugs

	2008	2009	2010	2011	2012	2013
Components of Growth						
Price Increases	**11.7%**	**11.6%**	**9.2%**	**8.2%**	**18.7%**	**11.6%**
New Drugs	**0.0%**	**1.5%**	**1.1%**	**3.5%**	**-**	**-**
Other	**3.7%**	**4.7%**	**6.1%**	**1.9%**	**-0.4%**	**2.5%**
Total Growth	**15.4%**	**17.8%**	**16.4%**	**13.6%**	**18.4%**	**18.4%**
Contribution to Overall Growth						
Price Increases	**76.0%**	**65.2%**	**56.1%**	**60.3%**	**101.6%**	**63.0%**
New Drugs	**0.0%**	**8.4%**	**6.7%**	**25.7%**	**-**	**-**
Other	**24.0%**	**26.4%**	**37.2%**	**14.0%**	**-2.2%**	**13.6%**
Total Growth	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2008-2013.

Exhibit 46
US Medicare Specialty Drug Trends
Price Increases as Largest Factor

	2010	2011	2012	2013
All US Medicare Specialty Drugs				
Cost	9.8%	11.6%	26.8%	15.3%
Utilization	2.9%	8.4%	-2.7%	-0.6%
Total Growth	12.7%	20.0%	24.1%	14.7%
Price Increases as % of Growth	77.2%	58.0%	111.2%	104.1%
Utilization as % of Growth	22.8%	42.0%	-11.2%	-4.1%
Multiple Sclerosis				
Cost	11.4%	14.1%	18.2%	14.1%
Utilization	9.6%	20.3%	8.5%	5.7%
Total Growth	21.0%	34.4%	26.7%	19.8%
Price Increases as % of Growth	54.3%	41.0%	68.2%	71.2%
Utilization as % of Growth	45.7%	59.0%	31.8%	28.8%
Inflammatory Conditions				
Cost	6.7%	8.3%	13.0%	13.6%
Utilization	3.4%	13.2%	7.4%	0.1%
Total Growth	10.1%	21.5%	20.4%	13.7%
Price Increases as % of Growth	66.3%	38.6%	63.7%	99.3%
Utilization as % of Growth	33.7%	61.4%	36.3%	0.7%
Cancer				
Cost	10.7%	14.7%	21.1%	16.3%
Utilization	5.8%	12.5%	11.8%	17.3%
Total Growth	16.5%	27.2%	32.8%	33.6%
Price Increases as % of Growth	64.8%	54.0%	64.3%	48.5%
Utilization as % of Growth	35.2%	46.0%	36.0%	51.5%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2013.

Exhibit 47

US Multiple Sclerosis Specialty Drug Market

Massive Price Increases Driving Growth

	2007	2008	2009	2010	2011	2012	2013
Components of Growth							
Price Increases	**12.4%**	**23.5%**	**24.8%**	**16.8%**	**16.1%**	**17.3%**	**14.7%**
New Drugs	**0.0%**	**0.0%**	**0.0%**	**2.7%**	**0.0%**	**-**	**-**
Other	**3.3%**	**-5.2%**	**7.7%**	**9.9%**	**2.1%**	**0.5%**	**1.0%**
Total Growth	**15.7%**	**18.3%**	**32.5%**	**29.4%**	**18.2%**	**17.8%**	**15.7%**
Contribution to Overall Growth							
Price Increases	**79.0%**	**128.4%**	**76.3%**	**57.1%**	**88.5%**	**97.2%**	**93.6%**
New Drugs	**0.0%**	**0.0%**	**0.0%**	**9.2%**	**0.0%**	**-**	**-**
Other	**21.0%**	**-28.4%**	**23.7%**	**33.7%**	**11.5%**	**2.8%**	**6.4%**
Total Growth	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2007-2013.

Exhibit 48

Biogen's Avonex Sales Trends: Tale of Two Worlds

	2008	2009	2010	2011	2012	Change 2008-2012
Revenues						
US	$1,277	$1,406	$1,492	$1,628	$1,794	41%
International	$926	$917	$1,027	$1,058	$1,119	21%
Worldwide	$2,203	$2,323	$2,518	$2,687	$2,913	32%
Revenues w/o Price Increases						
US	$1,020	$938	$882	$856	$838	
US Price % Growth	134%	179%	199%	133%	120%	
Volume Trend						
US	-6%	-8%	-6%	-3%	-2%	-25%
International	-	6%	6%	6%	8%	26%
Price Trend						
US	24%	18%	12%	12%	12%	78%
International 1	-	-7%	6%	-3%	-2%	-6%
Total Growth						Avg Growth
US	18%	10%	6%	9%	10%	14%
International	18%	-1%	12%	3%	6%	12%
Worldwide	18%	5%	8%	7%	8%	13%

1 International trend includes pricing, foreign exchange and other adjustments

Source: Biogen 10Ks 2007-2012

Exhibit 49

US Chronic Myeloid Leukemia (CML) Market

Massive Price Inflation Despite Rising Competition

Annual Cost of Therapy ($)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	Growth 2005-2013
Product										
Gleevec (NVS)	$29,376	$31,704	$34,212	$39,492	$45,528	$55,056	$63,540	$69,828	$76,716	161%
Tasigna (NVS)	-	-	47,880	52,596	60,660	66,672	68,724	68,724	72,108	-
Sprycel (BMY)	-	-	-	59,832	75,948	91,740	94,584	98,172	102,984	-
Bosulif (Pfizer)	-	-	-	-	-	-	-	-	98,172	-
Iclusig (Ariad)	-	-	-	-	-	-	-	-	114,960	-
Average	$29,376	$31,704	$34,212	$39,492	$45,528	$71,156	$75,616	$78,908	$83,936	186%

	Annual Change in Price							
	2006	2007	2008	2009	2010	2011	2012	2013
Gleevec (NVS)	8%	8%	15%	15%	21%	15%	10%	10%
Tasigna (NVS)	-	-	10%	15%	10%	3%	0%	5%
Sprycel (BMY)	-	-	-	27%	21%	3%	4%	5%
Bosulif (Pfizer)	-	-	-	-	-	-	-	-
Iclusig (Ariad)	-	-	-	-	-	-	-	-
Average	8%	8%	15%	15%	56%	6%	4%	6%

Source: Medi-Span.

Exhibit 50

Geographic Cost Comparison of Leading CML Therapies

Annual Cost per Patient

Data as of February 2013

	Gleevec (NVS)	Tasigna (NVS)	Sprycel (BMY)
United States	**$92,000**	**$115,500**	**$123,500**
Germany	**$54,000**	**$60,000**	**$90,000**
United Kingdom	**33,500**	**33,500**	**48,500**
Canada	**46,500**	**48,000**	**62,500**
Norway	**50,500**	**61,000**	**82,500**
France	**40,000**	**51,500**	**71,000**
Italy	**31,000**	**43,000**	**54,000**
South Korea	**$28,500**	**$26,000**	**$22,000**
Mexico	**29,000**	**39,000**	**49,500**
Argentina	**52,000**	**73,500**	**80,000**
Australia	**46,500**	**53,500**	**60,000**
Japan	**43,000**	**55,000**	**72,000**
China	**46,500**	**75,000**	**61,500**
Russia	**24,000**	**48,500**	**56,500**
South Africa	**43,000**	**28,000**	**54,500**

Source: Red Book.

Exhibit 51
Express Scripts Sources of Growth
All Recent Growth from Specialty Drugs

	Year-End		
Full Year 2010 and 2011	**2010**	**2011**	**Growth**
Traditional Pharmaceuticals	$30,148	$30,007	-0.47%
Specialty/Home Delivery Revenues	13,398	14,547	8.58%
Total	$43,546	$44,555	2.32%
Specialty % of Revenues	30.8%	32.7%	
Specialty % of Revenue Growth	-	113.9%	

	3Q
3Q 2012 - Post Medco Merger	**2012**
Traditional Pharmaceuticals	$16,342
Specialty/Home Delivery Revenues	9,580
Total	$25,922
Specialty % of Revenues	37.0%

Source: Express Scripts 2011 10K, page 40; Express Scripts 2012 3Q 10Q, page 54.

Exhibit 52

Type of PBM/Client Rebate Arrangement

By Employer Size

	Large Employer	Small Employer
Flat Rebate Guarantee/Rx	**32%**	**27%**
% Share of Rebates without Guarantee	**23%**	**15%**
% Share of Rebates with Minimum Guarantee	**27%**	**13%**
No Rebates	**11%**	**34%**
Do Not Know	**8%**	**11%**

Large Employer is > than 5,000 employees; Survey of 124 Large and 132 Small employers

Source: PBMI; 2012-2013 Prescription Drug Benefit Cost and Plan Design Report; page 28.

Exhibit 53

PBM Client Current Level of Specialty Drug Understanding:

Survey of 121 Employers and 60 Health Plans

	Employers	Health Plans
Low	**13.1%**	**3.3%**
Moderate	**68.0%**	**63.3%**
High	**18.9%**	**33.3%**

PBM Clients Seeking Further Specialty Drug Education:

	Employers	Health Plans
Definitely/Likely Yes	69.4%	88.3%
Definitely/Likely No	19.9%	8.4%
Not Sure	10.7%	3.3%

Source: PBMI; 2012-2013 Prescription Drug Benefit Cost and Plan Design Report; pages 22-24.

Exhibit 54

Keen PBM Client Interest in Specialty Drugs

Survey of 122 Employers and 60 Health Plans

Top Concerns Regarding Specialty Drugs	**Employers**	**Health Plans**
Overall Cost	45.9%	36.7%
Specialty Drug Price Increases	20.5%	20.0%
Appropriate Utilization	17.2%	30.0%
Other	16.2%	13.3%

Top Two Desired Outcomes for Managing Specialty Drugs	**Employers**	**Health Plans**
Decreasing Specialty Drug Costs	61.5%	61.7%
Total Healthcare Costs	50.8%	63.3%
Medical Adherence	32.0%	35.0%
Disease Progression	34.4%	26.7%
Quality of Life	21.3%	13.3%

Source: PBMI; 2012 Specialty Drug Benefit Report; pages 8 and 9

Exhibit 55

Key PBM Specialty Pharmacy Services

Nearly Identical Services Across Major PBMs - Little Targeted at Manufacturers

	Express Scripts	CVS/Caremark	Catamaran
Patients	Express shipping to home	Express shipping to home	Express shipping to home
	Education/Instruction materials	Education/Instruction materials	Education/Instruction materials
	Injection training	Injection training	Injection training
	Refill reminders	Refill reminders	Refill reminders
	On call 24/7 pharmacist	On call 24/7 pharmacist	On call 24/7 pharmacist
	Online community support	Online community support	Online community support
	Insurance counseling/assistance	Insurance counseling/assistance	Insurance counseling/assistance
	Care Coordination with physician office	Care Coordination with physician office	Care Coordination with physician office
	Welcome packet	Adherence check-ups via outreach calls	Initial phone consultation with firs Rx
	Monthly care coordinator call		Regular follow-up
Physicians	Express shipping to office	Express shipping to office	Express shipping to office
	Broad distribution network	Broad distribution network	Broad distribution network
	Prior authorization assistance	Prior authorization assistance	Easy Rx ordering/dedicated phone lines
	Specialty medication referral forms	Benefit verification/coordination	Prior authorization assistance
	Convenient ordering options	Vigilant monitoring with MD alerts	
Plan Sponsors	Coordinated account management	Help clients gain "control"	Broad drug access
	- Day-to-day specialty support	Strong patient support	Fast delivery
	- Regular strategic consultation	Increased adherence/minimize waste	Refill reminders
	Customized Reporting	Broad specialty drug access	Prior authorization assistance
	- Cost and dispensing reporting	Utilization management	Centralized technology
	- Utilization and outcome reporting		Share real-time data
	- Provider treatment and dispensing patterns		Clinical expertise/guidelines
	- Adherence and compliance reporting		
	- Plan benchmarking		
	Strategic Communication		
	- Outbound calls to patients		
	Continuous Quality Management		
	- Client satisfaction surveys		
	Patient satisfaction surveys		
	- Annual reviews/Quarterly reports		
	- Clinical management reports		
	- Annual strategic planning		
Manufacturers	None Listed	None Listed	Ensuring patient safety
			Achieving optimal product utilization
			Patient education/injection teaching
			Maintaining profitability/REMS programs

Source: Express Scripts, CVS Caremark and Catamaran websites.

Exhibit 56

Major PBM Specialty Drug Formularies: 2013

Nearly Identical Across Leading PBMs for Crowded Therapeutic Categories

	Express Scripts	CVS/Caremark	Catamaran [1]
Multiple Sclerosis			
	Avonex	**Avonex**	**AVONEX**
	Copaxone	**Copaxone**	**COPAXONE**
	Betaseron	**Betaseron**	**Betaseron**
	Rebif	**Rebif**	**REBIF**
	Extavia	**Extavia**	**Extavia**
	Gilenya	**Gilenya**	**Gilenya**
	Aubagio	**Aubagio**	**Aubagio**
	Tecfidera	**Tecfidera**	**Tecfidera**
		Tysabri	**Tysabri**
Rheumatoid Arthritis			
	Enbrel	**Enbrel**	**ENBREL**
	Humira	**Humira**	**HUMIRA**
	Orencia	**Orencia**	**Orencia**
	Simponi	**Simponi**	**Simponi**
	Xeljanz	**Xeljanz**	**Xeljanz**
	Kineret	**Kineret**	**Kineret**
	Cimzia	**Cimzia**	**Cimzia**
		Actemra	**Actemra**
		Remicade	**Remicade**
Chronic Myeloid Leukemia			
	Gleevec	**Gleevec**	**Gleevec**
	Tasigna	**Tasigna**	**Tasigna**
	Sprycel	**Sprycel**	**Sprycel**
	Bosulif	**Bosulif**	**Bosulif**
	Iclusig	**Iclusig**	**Iclusig**

1 Capitalized products are preferred in the Catamaran formulary

Source: 2013 national specialty drug formularies for Express Scripts, CVS/Caremark and Catamaran.

Exhibit 57
Medicare Part D Program Trends

Program Year	Total Expenditures ($bils)	Growth in Total Spending (%)	Spending Per Enrollee ($)	Growth in Spending Per Enrollee (%)
2006	$48.2	-	$1,746.38	-
2007	$49.7	3%	$1,582.80	-9%
2008	$49.4	-1%	$1,520.00	-4%
2009	$61.0	23%	$1,815.48	19%
2010	$61.7	1%	$1,778.10	-2%
2011	$67.4	9%	$1,887.96	6%
2012	$66.9	-1%	$1,793.57	-5%
2013E	$72.2	8%	$1,856.04	3%
2014E	$83.6	16%	$2,121.83	14%
2015E	$89.5	7%	$2,209.88	4%
2016E	$96.3	8%	$2,276.60	3%
2017E	$105.3	9%	$2,415.69	6%
2018E	$115.1	9%	$2,569.20	6%
2019E	$125.6	9%	$2,736.38	7%
2020E	$138.3	10%	$2,917.72	7%
2021E	$150.6	9%	$3,098.77	6%
2022E	$165.2	10%	$3,297.41	6%
Average Annual Growth				
2006-2013	6%		1%	
2013-2022	10%		7%	
Cumulative Growth				
2006 to 2013	50%		6%	
2013 to 2022	129%		78%	

Source: 2013 Annual Report from the Medicare Trustees.